To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP

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Related Clinical Coverage Policies
Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below: 9, *Outpatient Pharmacy Program*

1.0 Description of the Procedure, Product, or Service

This policy applies to safety monitoring for NC Medicaid (Medicaid) beneficiaries up to and including 17 years of age and NC Health Choice (NCHC) beneficiaries 6 through 17 years of age who are prescribed antipsychotic agents. Safety monitoring with documentation shall result when an antipsychotic medication is used without indications and dosage levels approved by the federal Food and Drug Administration (FDA). Safety monitoring shall target metabolic and neurologic side effects.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid and NCHC policies*)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

Note: Outpatient pharmacy services are available to all eligible Medicaid and Health Choice beneficiaries.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. <u>Medicaid</u>

None Apply.

b. <u>NCHC</u>

None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

None Apply.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**

b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
   1. No services for long-term care.
   2. No nonemergency medical transportation.
   3. No EPSDT.
   4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

The Department of Health and Human Services, NC Medicaid, may initiate a registration or prior authorization process for the off-label prescribing of an antipsychotic for a Medicaid beneficiary up to and including 17 years of age or a NCHC beneficiary 6 through 17 years of age to ensure safety monitoring documentation by the prescriber if:

a. The antipsychotic is prescribed for an indication that is not approved by the FDA.
b. The antipsychotic is prescribed at a different dosage than approved for an indication by the FDA.
c. The prescribed antipsychotic will result in the concomitant use of two or more antipsychotics.

5.1.1 Monitoring Portal for Prescriber Registry

Prescribers shall input information for each Medicaid beneficiary age 17 and under or NCHC beneficiary 6 through 17 for whom an antipsychotic agent is prescribed. The data elements collected are used to support a generally accepted clinical analysis of the safety and efficacy of the prescribed pharmacotherapy.

5.1.2 Safety Monitoring Documentation

A request for an antipsychotic medication meeting any of the descriptions as outlined below will require safety monitoring documentation by the prescriber in order for the claim to successfully complete point of sale processing.

a. An antipsychotic prescribed without a clinical diagnosis corresponding to an FDA approved indication.
b. An antipsychotic prescribed in an amount differing from the FDA approved dosage for that indication for a Medicaid beneficiary up to and including age 17 or an NCHC beneficiary 6 through 17 years of age.
c. An antipsychotic prescribed that meets the definition of intraclass polypharmacy*.

**Note: ***Intraclass polypharmacy is defined as combination therapy with two or more agents outside of a 60-calendar day window allowing for cross titration when converting agents.

5.1.3 Information Sources to Develop Monitoring Parameters

Safety monitoring parameters in the registry shall be based upon standards established by the American Psychiatric Association (APA), the American Academy of Child and Adolescent Psychiatry (AACAP), and currently accepted practice standards for the efficacious and safe use of antipsychotics in children and adolescents.

5.1.4 Provider Education

Providers shall be offered training and regular follow-up with a review of recent prescribing data. The initial education will focus on clinical issues related to the use of antipsychotics in children, including:

a. levels of evidence for use;
b. safety and outcomes assessments;
c. use of psychosocial supports; and
d. interventions to consider if adverse effects present during antipsychotic therapy.

Subsequent education will focus on clinical issues identified either statewide or at the specific practice level. Child psychiatry specialists shall be available as needed for consultative support.

5.1.5 Access Assured

If FDA approved guidelines for use are met for a specific beneficiary, further safety documentation is not required by the provider for a period of up to 365 days. The ability to bypass the documentation shall be granted on a beneficiary-specific basis. Systems will be built to assure beneficiaries will be able to obtain the appropriate medications as prescribed by the physician.

5.1.6 Indications and Maximum Dose Parameters

Selected antipsychotic agents have age dependent FDA approved indications and recommended dosage. Drug specific parameters by diagnosis shall be in accordance with the FDA guidelines.

5.1.7 Adverse Effects and Clinical Assessment Monitoring

Specific monitoring parameters recommended by the APA and the AACAP at baseline and predetermined therapy intervals may include Body Mass Index (BMI) percentile, blood pressure, glucose, lipid, complete blood count (CBC) and electrocardiogram (ECG). Parameters shall be monitored at baseline and then at recommended frequencies.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: April 12, 2011

Revision Information:

Date	Section Revised	Change
04/12/2011	Throughout policy (Medicaid)	Initial promulgation of new coverage
12/01/2011	Subsection 2.2 Prior Authorization (Medicaid)	Added wording to clarify process
12/01/2011	Subsection 2.4 Safety Monitoring Documentation (Medicaid)	Removed exceeding dose limitation
12/01/2011	Subsection 2.8 Indications and Maximum Dose Parameters (Medicaid)	Removed exceeding dose limitations
12/01/2011	Throughout policy (Medicaid)	Children/child/patient(s) without clinical context changed to recipient(s)
12/01/2011	Subsection 2.4 Safety Monitoring Documentation (Medicaid)	Replaced be filled by the pharmacy with successfully complete point of sale processing
12/01/2011	Subsection 2.9 Adverse Effects and Clinical Assessment Monitoring (Medicaid)	Replaced (such as overweight 25 -29.9; obese greater than or equal to 30) with percentile.
12/01/2011	Table 1 and Table 2 (Medicaid)	Deleted * and revised note explanation to clarify "Not recommended" comment in table
02/08/2012	Throughout (NCHC)	Initial promulgation of a new NCHC service, to be equivalent where applicable to NC DMA's Clinical Coverage Policy #A-6 under Session Law 2011-145.
03/12/2012	Throughout (Medicaid)	Policy number changed from A6 to 9D to be equivalent where applicable to NC DMA's Clinical Coverage Policy # 9D under Session Law 2011-145, § 10.41.(b).
03/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
07/01/2012	Table 1 and 2 (NCHC)	Deleted * and revised note explanation to clarify "Not recommended" comment in table
07/01/2012	Throughout	Changed recipient to beneficiary and recipients to beneficiaries
06/21/2013	Headers	Replaced period in Revised Date with a comma so it reads "July 1, 2012"
11/01/2013	Table 1	Added disorder after Bipolar I
11/01/2013	Table 1	Added Paliperidone for Schizophrenia
11/01/2013	Table 1	Added olanzapine & fluoxetine for Bipolar Disorder
11/01/2013	Table 2	Added drug Olanzapine & fluoxetine
11/01/2013	Table 2	Added drug Paliperidone
11/01/2013	References	Added Up to Date online

Date	Section Revised	Change
11/01/2014	Table 1	Revised Risperidone dose from 6mg to 3mg
11/01/2014	References	Added Risperdal Product Information
11/01/2014	All Sections and Attachments	Reviewed policy grammar, readability, typographical accuracy, and format. Policy amended as needed to correct, without affecting coverage. Updated policy template language.
2/2/2015	Table 1	Added Aripiprazole for indication of Tourette's Disorder
2/2/2015	References	Added Abilify Product Information
04/01/2015	Table 1	Added Asenapine for indication of Bipolar Disorder
04/01/2015	Table 2`	Added maximum dose for Asenapine
04/01/2015	References	Added Saphris Product Information
10/01/2015	Subsection 5.1.6	Removed, "Refer to Table 1 and Table 2"
10/01/2015	Subsection 5.1.6	Removed Table 1
10/01/2015	Subsection 5.1.6	Removed Table 2
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/12/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/12/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".

Attachment A: Claims related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Online Real-Time Point of Sale using the current version of the National Council for Prescription Drug Program (NCPDP)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Does not apply

C. Code(s)

Does not apply

D. Modifiers

Does not apply

E. Billing Units

The National Drug Code (NDC) determines the billing unit(s).

F. Place of Service

Active Medicaid or NCHC pharmacy provider

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

For NCHC refer to NCHC State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

Refer to clinical coverage policy 9, *Outpatient Pharmacy Program*; **Attachment A: Claims-Related Information; B**: Directions for Drug Reimbursement, on NC Medicaid's website at: https://medicaid.ncdhhs.gov/

Attachment B: References

1. Walkup J, ed. Practice Parameter on the use of Psychotropic Medication in Children and Adolescents. J Acad Child Adolesc Psychiatry 2009. 48 (9). 961-973.

2. Fedorowicz VJ, Fombonne E. Metabolic side effects of atypical antipsychotics in children: a literature review. J Psychopharmacol 2005. 19(5). 533-50.

3. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. American Diabetes Association-American Psychiatric Association. Diabetes Care 2004. 27(2). 596-601.

4. Kumra S, Oberstar JV, Sikich L, et. al. Efficacy and tolerability of second-generation antipsychotics in children and adolescents with schizophrenia. Schizophrenia Bulletin 2008. 34(1): 60-71.

5. Correll CU, Carlson HE. Endocrine and metabolic adverse effects of psychotropic medications in children and adolescents. J. Am.Acad.Child.Adolesc.Psychiatry 2007. 45:7. 771-791.

6. Correll CU, Kane JM. One-year incidence rates of tardive dyskinesia in children and adolescents treated with second generation antipsychotics: a systematic review. J Child Adolesc Psychopharmacol 2007. 17(5): 647-56.

7. Zito JM, Derivan AT, Kratochvil CJ, et al. Off-label psychopharmacologic prescribing for children: History supports close clinical monitoring. Child and Adolescent Psychiatry and Mental Health 2008. 2:24; 1-11.

8. Publication Committee Medicaid Medical Directors Learning Network/Rutgers Center for Education and Research on Therapeutics. Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study. Institute of Health, Healthcare Policy and Aging Research, Rutgers University. Publication Number 1, June 2010. http://rci.rutgers.edu/~cseap/MMDLNAPKIDS.html. Accessed 9/20/2010.

9. Facts & Comparisons® E Answers. http://www.factsandcomparisons.com/. Accessed 7/22/11;

10. Lexicomp Online. http://online.lexi.com.libproxy.lib.unc.edu/crlsql/servlet/crlonline. Accessed 7/25/2011

11. UpToDate Online. http://www.uptodate.com/home. Accessed 10/11/2013.

12. Risperdal Product Information. http://www.janssenpharmaceuticalsinc.com/assets/risperdal.pdf

13. Abilify Product Information. http://www.otsuka-us.com/Documents/Abilify.PI.pdf

14. Saphris Product Information
http://pi.actavis.com/data_stream.asp?product_group=1908&p=pi&language=E

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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Related Clinical Coverage Policies
Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:
9 *Outpatient Pharmacy Program*

1.0 Description of the Procedure, Product, or Service

This policy applies to safety monitoring for NC Medicaid (Medicaid) beneficiaries age 18 and older who are prescribed antipsychotic agents. Safety monitoring with documentation shall result when an antipsychotic medication is used without indications and dosage levels approved by the federal Food and Drug Administration (FDA). Safety monitoring shall target metabolic and neurologic side effects.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid and NCHC policies*)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

Note: Outpatient pharmacy services are available to all eligible Medicaid and NCHC beneficiaries

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. <u>Medicaid</u>
None Apply.

b. <u>NCHC</u>
NCHC beneficiaries are not eligible for Off Label Antipsychotic Safety Monitoring In Beneficiaries 18 and Older.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing*

Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

None Apply.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.21 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
    1. No services for long-term care.
    2. No nonemergency medical transportation.
    3. No EPSDT.
    4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

The Department of Health and Human Services, NC Medicaid, may initiate a registration or prior authorization (PA) process for the off label prescribing of an antipsychotic for a beneficiary age 18 and older to ensure safety monitoring documentation by the prescriber if:

a. The antipsychotic is prescribed for an indication that is not approved by the FDA.
b. The antipsychotic is prescribed at a different dosage than approved for an indication by the FDA.
c. The prescribed antipsychotic results in the concomitant use of two or more antipsychotics.

5.1.1 Exemptions

Beneficiaries with any of the following diagnoses are exempt from the registration or PA requirements of the policy.

a. Schizophrenia
b. Schizophreniform disorder
c. Schizoaffective disorder
d. Delusional disorder
e. Brief psychotic disorder
f. Shared psychotic disorder
g. Psychotic disorder Not Otherwise Specified (NOS)
h. Bipolar disorder
i. Major depressive disorder with psychotic features
j. Treatment resistant depression (antipsychotic use for TRD is adjunctive only)
k. Tourette syndrome
l. Other psychoses

The pharmacist may override the PA edit at point of sale if the prescriber writes on the face of the prescription in his or her own handwriting: **"Meets PA Criteria."** This information may also be entered in the comment block on e-prescriptions.

5.1.2 Monitoring Portal for Prescriber Registry

Prescribers shall input information for each beneficiary age 18 and older for whom an antipsychotic is prescribed that meet any of the criteria listed in **Subsection 5.1.1**. The data elements collected are used to support a generally accepted clinical analysis of the safety and efficacy of the prescribed pharmacotherapy.

5.1.3 Safety Monitoring Documentation

A request for an antipsychotic medication meeting any of the descriptions as outlined below will require safety monitoring documentation by the prescriber in order for the claim to successfully complete point of sale processing.

a. An antipsychotic prescribed without a clinical diagnosis corresponding to an FDA approved indication.
b. An antipsychotic prescribed in an amount differing from the FDA approved dosage for that indication for a beneficiary 18 years of age and older
c. An antipsychotic prescribed that meets the definition of intraclass polypharmacy*****.

**Note: ***Intraclass polypharmacy is defined as combination therapy with two or more agents outside of a 60 calendar day window allowing for cross titration when converting agents.

5.1.4 Information Sources to Develop Monitoring Parameters

Safety monitoring parameters in the registry shall be based upon standards established by the American Psychiatric Association (APA) and currently accepted practice standards for the efficacious and safe use of antipsychotics.

5.1.5 Provider Education

Providers shall be offered training and regular follow-up with a review of recent prescribing data. The initial education will focus on clinical issues related to the use of antipsychotics including:

a. levels of evidence for use;
b. safety and outcomes assessments;
c. use of psychosocial supports; and
d. interventions to consider if adverse effects present during antipsychotic therapy.

Subsequent education will focus on clinical issues identified either statewide or at the specific practice level. Psychiatry specialists shall be available as needed for consultative support.

5.1.6 Access Assured

If FDA approved guidelines for use are met for a specific beneficiary, further safety documentation will not be required by the provider for a period of up to 365 days. The ability to bypass the documentation shall be granted on a beneficiary specific basis. Systems will be built to assure beneficiaries will be able to obtain the appropriate medications as prescribed by the physician.

5.1.7 Indications and Maximum Dose Parameters

Selected antipsychotic agents have age dependent FDA approved indications and recommended dosages. Drug specific parameters by diagnosis shall be in accordance with the FDA guidelines.

5.1.8 Adverse Effects and Clinical Assessment Monitoring

Specific monitoring parameters recommended by the APA and other evidence based sources at baseline and predetermined therapy intervals may include Body Mass Index (BMI) percentile, blood pressure, glucose, lipid, complete blood count (CBC) and electrocardiogram (ECG). Parameters shall be monitored at baseline and then at recommended frequencies.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

a. meet Medicaid or NCHC qualifications for participation;
b. be currently Medicaid - enrolled; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: March 20, 2012

Revision Information:

Date	Section Revised	Change
03/20/2012	Throughout policy	Initial promulgation of new coverage for Medicaid
03/20/2012	Sub-Section 2.2.1	Additional diagnoses h. – l. were added to the list of exemptions; procedures for point of sale override were added
07/01/2012	Throughout	Policy number changed from A7 to 9E. Technical changes to merge Medicaid and NCHC current coverage into one policy
07/01/2012	Throughout	Change recipient and beneficiary and recipient to beneficiaries
11/01/2013	Section 5.0 Table 1	Latuda max dose changed to 160mg and bipolar depression indication added
11/01/2013	References	Added Up to Date Online
11/01/2014	Table 1	Added Abilify Maintena
11/01/2014	References	Added Abilify Product Information
11/01/2014	All Sections and Attachments	Reviewed policy grammar, readability, typographical accuracy, and format. Policy amended as needed to correct, without affecting coverage. Updated policy template language.
02/02/2015	Table 1	Added Aripiprazole for indication of Tourette's Disorder
10/01/2015	Section 5.1.7	Removed "Refer to Table 1"
10/01/2015	Section 5.1.7	Removed Table 1
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/12/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/12/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Online Real-Time Point of Sale using the current version of the National Council for Prescription Drug Program (NCPDP).

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Does not apply.

C. Code(s)

Does not apply.

D. Modifiers

Does not apply.

E. Billing Units

The National Drug Code (NDC) determines the billing unit(s).

F. Place of Service

Active Medicaid pharmacy provider

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

For NCHC refer to NCHC State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

Refer to clinical coverage policy 9 *Outpatient Pharmacy Program*; Attachment A: Claims Related Information; B: Directions for Drug Reimbursement, indexed at: https://medicaid.ncdhhs.gov/

Attachment B: References

1. Buchanan RW, Kreyenbuhl J, Kelly DL, et al. The 2009 PORT psychopharmacological treatment recommendations and summary statements. Schizophrenia Bulletin 2009; (36) 1, 71-93.
2. Consensus Development Conference on Antipychotic Drugs and Obesity and Diabetes. American Diabetes Association-American Psychiatric Association. Diabetes Care 2004. 27(2). 596-601.
3. Dixon L, Perkins D, Calmes C. Guideline Watch (September 2009): Practice guideline for the treatment of patients with schizophrenia. American Psychiatric Association. Available at http://www.psychiatryonline.com/pracGuide/PracticePDFs/Schizophrenia_Guideline%20Watch.pdf Accessed 8/25/2010.
4. Kreyenbuhl J, Buchanan RW, Dickerson FB, et al. The schizophrenia patient outcomes research team (PORT): updated treatment recommendations. Schizophrenia Bulletin 2009; (36) 1, 94-103.
5. Marder SR, Essock SM, Miller AL. The Mount Sinai conference on the pharmacotherapy of schizophrenia. Schizophrenia Bulletin 2002. 28(1): 5-16.
6. Parks J, Svendsen D, Singer P, et al. eds. Morbidity and Mortality in People with Serious Mental Illness. National Association of State Mental Health Program Directors. October 2006. www.nasmhpd.org. Accessed 8/24/2010.
7. Rosenheck RA, Leslie DL, Busch SB, et al. Rethinking antipsychotic formulary policy. Schizophrenia Bulletin 2008; (34) 2, 375-380.
8. Rosenheck RA. Outcomes, costs, and policy caution. A commentary on the Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1). Arch Gen Psychiatry 2006. 63: 1074-1076.
9. Sicouri S, Antzelevitch C. Sudden cardiac death secondary to antidepressant and antipsychotic drugs. Expert Opinion on Drug Safety 2008. 7(2):181-194.
10. UpToDate Online. http://www.uptodate.com/home. Accessed 10/11/2013.
11. Abilify Product Information. http://www.otsuka-us.com/Products/Documents/Abilify.M.PI.pdf
12. Abilify Product Information. http://www.otsuka-us.com/Documents/Abilify.PI.pdf

Therapeutic Class Code: A7G
Therapeutic Class Description: C-GMP Type 5 Inhibitor

Medication	Generic Code Number(s)
Cialis 2.5mg tablet and generic tadalafil 2.5mg tablet	99409
Cialis 5mg tablet and generic tadalafil 5mg tablet	20736

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
http://www.ncdhhs.gov/dma/basicmed/

EPSDT provider page: https://medicaid.ncdhhs.gov/programs-and-services/medical/wellness-visits-and-diagnostic-and-treatment-services

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

- Beneficiary is 18 or older
  AND
- Beneficiary is a male
  AND
- Beneficiary has confirmed diagnosis of Benign Prostatic Hyperplasia
  AND
- Beneficiary has no concurrent therapy with an alpha blocker or nitrates
  AND
- Beneficiary has tried and failed all preferred medications
  AND
- May not be prescribed for Erectile Dysfunction (ED)

Procedures:

1. Approve for 1 year
2. Changes in strength do not require a new prior approval.

References

1. Prescriber Information - Cialis ® (tadalafil) Eli Lilly and Company, Indianapolis, Indiana 46285. October 2011.

Criteria Change Log

11/14/2012	Criteria effective date
09/23/2019	Added generic tadalafil

WellCare of North Carolina
Prior Authorization Criteria
Emflaza

Effective Date: 04/03/18

Therapeutic Class Code: P5A
Therapeutic Class Description: Glucocorticoids

Medication
Emflaza™

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of

Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or
ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to
correct or improve or maintain the beneficiary's health in the best condition possible, compensate fora health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid- benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage:

- The beneficiary is 2 years of age or older.
- Documentation is submitted that the beneficiary has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic testing.
- Documentation is submitted that the beneficiary has tried prednisone and has had inadequate treatment response or has experienced unmanageable and clinically significant side effects such as significant weight gain/obesity, persistent psychiatric/behavioral issues, diabetes, hypertension, or Cushingoid appearance.
- A baseline motor milestone assessment (such as 6-minute walk test (6MWT), North Star Ambulatory Assessment (NSAA), Motor Function Measure (MFM), or Hammersmith Functional Motor Scale (HFMS)) has been done and documentation submitted.
- Medication is prescribed by or in consultation with a neurologist
- Emflaza™ is not given concurrently with live vaccinations.
- Emflaza™ dosing for Duchenne Muscular Dystrophy is in accordance with the USFDA approved labeling.
- Maximum length of initial approval: 6 months

Criteria for Renewal Coverage:

- Documentation must be submitted that shows the beneficiary is receiving clinical benefit from Emflaza™ therapy, such as stabilization, maintenance or improvement of muscle strength or pulmonary function, or improvement in motor milestone assessment scores from baseline testing, or motor function must be superior relative to that projected for the natural course of Duchenne Muscular Dystrophy (slowing of decline or slowing of progression).
- Maximum length of renewal approval: 12 months

References

1. Prescriber Information Emflaza ™ (deflazacort) Marathon Pharmaceuticals, LLC Northbrook IL, 60062. February 2017. Update June 2019.

Criteria Change Log

04/03/2018	Criteria effective date
12/06/2019	Age change to 2 and up

Therapeutic Class Code: A4L
Therapeutic Class Description: Angiotensin II Receptor Blocker-Neprilysin Inhibitor Comb. (ARNi)

Medication	Generic Code Number(s)	NDC Number(s)
Entresto	39046, 39047, 39048	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

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https://medicaid.ncdhhs.gov//

EPSDT provider page: https://medicaid.ncdhhs.gov/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

- Beneficiary has a diagnosis of chronic heart failure (NYHA class II-IV) with a left ventricular ejection fraction (EF) less than or equal to 40%. **AND**
- Beneficiary does not have a history of angioedema related to therapy with an ACE inhibitor or ARB. **AND**
- If the beneficiary is currently taking an ACE inhibitor or ARB, Entresto will replace that current therapy. **AND**
- If the beneficiary has diabetes, he or she is not taking a medication containing aliskiren (e.g. Tekturna or Tekturna HCT). **AND**
- Reauthorization requests must include documentation that the beneficiary is receiving clinical benefit from the medication such as stabilization of symptoms, improvement or stability of EF, or a reduction in hospitalizations.

Procedures:

- Approval up to 1 year.

References:

Prescriber Information-Entresto ® Novartis Pharmaceuticals East Hanover, NJ 07936, August 2015.

Criteria Change Log

11/01/2016	Criteria effective date
02/26/2019	Add continuation criteria
07/15/2019	Remove beta blocker requirement

WellCare of North Carolina
Prior Authorization Criteria
Epinephrine Auto-Injections

Effective Date: 12/05/18
Amended Date: 10/02/19

Therapeutic Class Code: J5F
Therapeutic Class Description: Epinephrine injection

Medication
Epinephrine Pen (generic)
EpiPen 2-Pak
EpiPen Jr 2-Pak
Symjepi injection

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery f the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.

b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaids-benefit-children-and-adolescents.

Criteria:

Exceeding Quantity Limit of 6 Pens per 180 days:

Prescriber must submit reason of medical necessity stating reasons the quantity limit needs to be exceeded.

Procedures:

Prior authorization request forms will be accepted when submitted by mail, facsimile telecommunication or web portal.

References:

1. Dey Pharma L.P. EpiPen package insert. Maryland: August 2012.
2. Sanofi-aventis LLC. Auvi-Q package insert. New Jersey: September 2012.
3. Amedra Pharmaceuticals LLC, Horsham, PA, Adrenaclick. 2013
4. Adamis Pharmaceutical Corporation. Symjepi prescribing information. San Diego, CA: Revised June 2017.

Criteria Change Log

01/01/2015	Criteria effective date
12/05/2018	Removed Auvi-Q due to non-rebate status
10/02/2019	Removed Adrenaclick- no longer manufactured. Add Symjepi.

WellCare of North Carolina
Prior Authorization Criteria
Gocovri and Osmolex ER

Effective Date: 02/26/19
Amended Date: 10/14/19

Therapeutic Class Code: H6A
Therapeutic Class Description: Drugs to Treat Movement Disorders

Medication	Generic Code Number(s)	NDC Number(s)
Gocovri	43787, 43788	
Osmolex ER	44471, 44472, 44473	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IFPRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents.

Criteria for Initial Coverage of Gocovri:

- Beneficiary has a diagnosis of dyskinesia due to Parkinson's disease and is receiving levodopa-based therapy, with or without dopaminergic medications
- Beneficiary is age 18 or older
- Beneficiary has no contraindications including ESRD (creatinine clearance <15 ml/min/1.73m^2
- Beneficiary has failure, contraindication, or intolerance to immediate-release amantadine (capsule, tablet, or oral solution)
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage of Gocovri:

- All of the above criteria for initial coverage of Gocovri are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

Criteria for Initial Coverage of Osmolex ER:

- Beneficiary has a diagnosis of Parkinson's disease or Drug-induced extrapyramidal reactions
- Beneficiary is age 18 or older
- Beneficiary has no contraindications including ESRD (creatinine clearance <15 ml/min/1.73m^2
- Beneficiary has failure, contraindication, or intolerance to immediate-release amantadine (capsule, tablet, or oral solution)
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage of Osmolex ER:

- All of the above criteria for initial coverage of Osmolex ER are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

References

1. Prescriber Information – Gocovri. Adamas Pharmaceuticals, Inc. Emeryville, CA. Revised 08/2017.
2. Prescriber Information- Osmolex ER. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. Revised 07/2018.

Criteria Change Log	
02/26/2018	Criteria effective date
10/14/2019	Added criteria for Osmolex ER. Added for age 18 and over to Gocovri. Clarified on continuation on Gocovri that you must have met the initial criteria for Gocovri in order to have approval for continuation of coverage. Added Osmolex to title

WellCare of North Carolina
Prior Authorization Criteria
Hematinics

Effective Date: 03/04/02
Revised Date: 11/07/19

Therapeutic Class Code: N1B
Therapeutic Class Description: Hematinics, Other

Medication	Generic Code Number(s)	NDC Number(s)
Procrit, Epogen (Erythropoietin)	24059, 25110, 25111, 25112, 25113, 25114, 25115	
Aranesp (Darbepoetin Alfa)	14049, 14053,14054, 14055,14056, 14877,14891, 14893, 14894, 15202, 27164, 97063, 97064, 97065, 97066	
Mircera	98890, 98891, 98893	
Retacrit	44764, 44765, 44766, 44767, 44768	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHCbeneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service

requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Approval will be considered in the following circumstances:

1. Anemia associated with renal failure **OR**
2. Anemia associated with HIV Infection **OR**
3. Anemia associated with chemotherapy **OR**
4. Anemia associated with myelodysplastic syndromes **OR**
5. Drug induced anemia such as with ribavarin or zidovudine

Initial Therapy - Beneficiary shall meet all requirements:

1. Hemoglobin less than or equal to 11 for initial therapy **AND**

2. Lab data within 3 months of PA

Continuation of Therapy - Beneficiary must meet all requirements:

1. Hemoglobin less than or equal to 12 AND
2. Lab data within 3 months of PA

Procedures

May be approved for up to sixmonths.

References

1. Epoetin alfa. Drug facts and comparisons. St. Louis (MO): Facts and Comparisons, Inc; Clinisphere 2.0 Tutorial; 2001.
2. Ortho-Biotech, Inc. Procrit package insert. Thousand Oaks (CA): 1999 Oct.
3. Turner R et al. Epoetin alfa in cancer patients; evidence-based guidelines. J Pain Symptom Manage 2001 Nov;22 (5):954-65.
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5. Abrams DI, Steinhart C and Frascino R. Epoetin alfa therapy for anaemia in HIV-infected patients: impact on quality of life. Int J STD AIDS 2000 Oct; 11(10):659-65.
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10. NEJM editorial Remuzzi G, Ingelfinger JR. Correction of anemia – payoff and problems. NEJM. 2006. 355(20): 2144-2146.
11. Systematic review of the literature. Ross SD, Allen E, Henry DH, Seaman C, Sercus B, Goodnough LT. Clinical benefits and risks associated with epoeitin and darbepoetin in patients with chemotherapy induced anemia: a systematic review of the literature. Clinical Therapeutics. 2006. 28(6): 801-831.
12. Retacrit Prescribing information. Pfizer Labs. New York, NY 10017. January 2019.
13. Mircera Prescribing Information. Vifor Pharma. Switzerland. June 2018.

Criteria Change Log

04/04/2002	Criteria effective date (Procrit and Epogen)
07/01/2003	Added criteria for Aranesp
11/01/2014	Added new codes for Aranesp
02/25/2019	Removed discontinued GCN 97072
11/07/2019	Added Mircera and Retacrit

WellCare of North Carolina
Prior Authorization Criteria
Hetlioz (tasimelteon) Effective Date: 03/16/15

Therapeutic Class Code: H8B
Therapeutic Class Description: Hypnotics, Melatonin MT1/MT2 Receptor Agonists

Medication	Generic Code Number(s)	NDC Number(s)
Hetlioz	36068	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
http://www.ncdhhs.gov/dma/basicmed/

EPSDT provider page: http://www.ncdhhs.gov/dma/epsdt/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

- Beneficiary must be 18 years of age or older.

AND

- Beneficiary has a documented diagnosis of Non-24 sleep-wake disorder.
    - The diagnosis of Non-24 is confirmed by meeting ONE of the following conditions:
        - **i.** Assessment of at least one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset [as measured in blood or saliva], assessment of core body temperature);

        OR

        - **ii.** If assessment of at least one physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for ≥ 1 week plus evaluation of sleep logs recorded for ≥ 1 month.

AND

- Beneficiary is blind.

AND

- Beneficiary has had an insufficient response or intolerance to at least two (2) other medications for sleep.

AND

- The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders.

Procedures:

- Coverage is limited to a maximum of 30 capsules per 30 days.

- Initial approval is limited to a period of 3 months.
- For continuation of therapy, beneficiary's use of Hetlioz must be continuous without gaps in treatment and the prescriber must provide an objective evaluation of the beneficiary's sleep quality, including documentation of an improvement in overall sleep quality while taking Hetlioz.
- Continuation approvals may be up to a period of 6 months.

References

1. Prescriber Information-Hetlioz ® (tasimelton) Vanda Pharmaceuticals Inc. Washington DC 20037, January 2014.

Criteria Change Log

03/16/2015	Criteria effective date

WellCare of North Carolina
Prior Authorization Criteria
Lupus Medications

Effective Date: 04/05/18

Therapeutic Class Code: Z2Y
Therapeutic Class Description: Immunosuppresive Agents; Miscellaneous; Immunomodulator, B-Lymphocyte Stim (BLYS)-Specific Inhibitor

Medication	Generic Code Number(s)	NDC Number(s)
Benlysta®	43658, 43661, 29633, 29634	49401008835, 49401008801, 49401008842, 49401008847, 49401010101, 49401010201

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may haveservice restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate adefect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method ofmedical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under

21 years of age does **NOT** eliminate the requirement for prior approval.

b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
http://www.ncdhhs.gov/dma/basicmed/

EPSDT provider page: http://www.ncdhhs.gov/dma/epsdt/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of active systemic lupus erythematosus (SLE)
- Benlysta is prescribed by or in consultation with a rheumatologist
- Beneficiary must be auto-antibody positive
- Beneficiary must be utilizing Benlysta in combination with standard treatment regimens (NSAIDs, corticosteroids, anti-malarials, and immunosuppressive drugs) or standard treatment regimens were not tolerated or not beneficial.
- Beneficiary must not have a diagnosis of severe active lupus nephritis or severe active central nervous system lupus, or concurrently use other biologics and/or IV cyclophosphamide.
- Maximal length of approval: 12 months

Criteria for Renewal Coverage:

- There is documented improvement in functional impairment such as 1) fewer flares that required steroid treatment; 2) lower average daily oral prednisone dose; 3) improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits; 4) sustained improvement in laboratory measures of lupus activity.
- Maximum length of approval: 12 months

Subsequent authorizations will be granted based on current progress notes from the physician documenting disease status and clinical response.

References:

Benlysta full prescribing information. Rockville, MD: Human Genome Sciences, Inc.

Criteria Change Log

04/05/2018	Criteria effective date

Therapeutic Class Code: S7A
Therapeutic Class Description: Neuromuscular Blocking Agents

Medication	Generic Code Number(s)
Botox (onabotulinumtoxin A)	23360, 28011
Myobloc (rimabotulinumtoxin B)	12245, 12246, 12247
Dysport (abobotulinumtoxin A)	23361, 29243
Xeomin (incobotulinumtoxin A)	27767, 28953

Eligible Recipients
Medicaid recipients must be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NCHC recipients, ages 6 through 18 years of age, must be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

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EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to

correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
http://www.ncdhhs.gov/dma/basicmed/

EPSDT provider page: http://www.ncdhhs.gov/dma/epsdt/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Recipients ages 6 through 18 years of age

EPSDT does not apply to NCHC recipients. If a NCHC recipient does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC recipient will be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes will be covered for NCHCrecipients.

Criteria:

Onabotulinumtoxin A (Botox):

Onabotulinumtoxin A (Botox) shall be covered as follows:

FDA-Indications:

- Blepharospasm
- Disorders of eye movement (strabismus)
- Spasmodic Torticollis, secondary to cervical dystonia
- Upper limb and lower limb spasticity in adults
- Chronic Migraine (Botox ONLY) age 18 and older:
    - 15 or more days each month with headache lasting 4 or more hours

      and

    - tried and failed prophylactic medications from at least 3 different drug classes (beta blockers, calcium channel blockers, tricyclic antidepressants and anticonvulsants) each for at least 3 months of therapy

or

- has a documented contraindication, intolerable side effects, or allergy to prophylactic medications (beta blockers, calcium channel blockers, tricyclic antidepressants and anticonvulsants)

and

- Initial approval will be for 6 months
- For continuation of therapy:
  - assessment of response should be noted after the first 2 injections (6 months)
  - average number of headache days decreased by 6 or more days from the patient's baseline headache frequency

- Urinary Incontinence and Overactive Bladder (Botox ONLY):
  - due to detrusor overactivity (idiopathic or associated with neurologic conditions)

    and

  - tried and failed an anticholinergic medication

    or

  - has a documented contraindication, intolerable side effects, or allergy to anticholinergic medications

- Severe axillary hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met:
  - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
  - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant

Off-Label Indications:

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated

- Spasticity (e.g., from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia , hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, and stroke)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Achalasia and cardiospasm
- Secondary focal hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Abobotulinumtoxin A (Dysport):

Abobotulinumtoxin A (Dysport) shall be covered for the following conditions:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia
- Upper limb spasticity in adults
- Lower limb spasticity in pediatric patients 2 years of age and older

- Off-label indications:

- Blepharospasm
- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated
- Spasticity (e.g., from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, stroke, and upper limb spasticity inadults)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Disorders of eye movement (strabismus)
- Achalasia and cardiospasm
- Secondary focal hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Severe axillary hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be

met:
    - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
    - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Incobotulinumtoxin A (Xeomin):

Incobotulinumtoxin A (Xeomin) shall be covered as follows:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia
- Blepharospasm
- Upper limb spasticity in adults

Off-label indications:

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated
- Spasticity (e.g., from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, stroke, and upper limb spasticity in adults)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Disorders of eye movement (strabismus)
- Achalasia and cardiospasm
- Secondary focal hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Severe axillary hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met:
    - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
    - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Rimabotulinumtoxin B (Myobloc):

Rimabotulinumtoxin B (Myobloc) shall be covered for the following conditions:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia

Off-label indications:

- Sialorrhea

There are several botulinum toxins, currently A through G. Only A and B are now FDA-approved and commercially available. This policy deals *only* with onabotulinumtoxin A (Botox), abobotulinumtoxin A (Dysport), incobotulinumtoxin A (Xeomin) and rimabotulinumtoxin B-(Myobloc). These share certain properties, and some FDA approvals, as well as certain off-label uses that are addressed in this policy. However, these agents are *not* identical, and have differing therapeutic and adverse event profiles. Furthermore, units and dosing are not equivalent, so they are not directly interchangeable with one another. It is expected that physicians familiar with and experienced in use of these agents will utilize evidence-based medicine to select the appropriate drug and dose regimen for each recipient, condition, and use.

Procedures:

1) Not approved for cosmetic purposes

2) Approval length up to 12 months

3) Dosage limitations for onabotulinumtoxin A (Botox): the cumulative dosage should not exceed 600 units per 90 days.

4) Dosage limitations for rimabotulinumtoxin B (Myobloc): 10,000 units per 12 weeks (84 days).

5) Dosage limitations for abobotulinumtoxin A (Dysport): 1500 units per 12 weeks (84 days)

6) Dosage limitations for incobotulinumtoxin A (Xeomin): 500 Units per 12 weeks (84 days)

References:

1. Lim M, Mace A, Nouraei SA, Sandhu G Botulinum toxin in the management of sialorrhea: a systemic review. Clinical Otolaryngol. 2006 Aug; 31(4) 267-72

2. Allergan Pharmaceuticals, Inc. Botox package insert. Irvine (CA); Revised September 2013

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4. Cheng CM, Chen JS, Patel RP. Unlabeled Uses of Botulinum Toxins: A Review, Part 1. Am J Health-Syst Pharm. 2005; 63(2):145-152. Accessed through http://www.medscape.com on February 6, 2006.

5. Cheng CM, Chen JS, Patel RP. Unlabeled Uses of Botulinum Toxins: A Review, Part 2. Am J Health-Syst Pharm. 2006; 63(3):225-232. Accessed through http://www.medscape.com on March 8, 2006.

6. Sycha T, Kranz G, Auff E, Schnider P. Botulinum toxin in the treatment of rare head and neck pain syndromes: a systematic review of the literature. J Neurol (2004) 251 [Suppl 1]; I/19-I/30.

7. Wasiak J, Hoare B, Wallen M. Botulinum toxin A as an adjunct to treatment in the management of the upper limb in children with spastic cerebral palsy. The Cochrane Database of Systematic Reviews 2004, Issue 4. Art. No.: CD003469.pub3. DOI: 10.1002/14651858.CD003469.pub3.

8. North Carolina State Health Plan. Clostridium Botulinum Neurotoxins. Medco Health Solutions, April 2005.

9. Ipsen Biopharm Ltd., Dysport package insert. Wrexham, LL13, 9UF,UK and Brisbane, CA; May 2009.

10. Merz Group Services GmbH; Xeomin package insert. Dessau-Rosslau, Germany and Greensboro, NC; 2010.

11. Cephalalgia. 2010 Jul; 30 (7): 793-803 and 804-814.Epub 2010 Mar 17.

12. Nitti VW, Dmochowski R, Herschorn S, et al. OnabotulinumtoxinA for the treatment of patients with overactive bladder and urinary incontinence: results of a phase 3, randomized, placebo controlled trial. *J Urol*. 2013;189:2186-93.

13. Botox Prescribing Information. Allergan Inc., Irvine, CA 92612. Updated January 2016.

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15. Merz Group Services GmbH; Xeomin package insert. Dessau-Rosslau, Germany and Greensboro, NC; 12/2015.

Criteria Change Log	
03/04/2002	Criteria effective date
03/26/2007	Addition: Botulinum Toxin Type A (Botox): Medicaid covers botulinum toxin type A (Botox) for the following conditions: • Chronic anal fissure refractory to conservative treatment • Esophageal achalasia patients in whom surgical treatment is not indicated\ • Blepharospasm • Spasmodic Torticollis, secondary to cervical dystonia • Hereditary spastic paraplegia • Multiple Sclerosis for patients with spasticity • Neuromyelitis Optica for patients with spasticity secondary to spinal cord involvement • Other Demyelinating diseases of central nervous system with secondary spasticity • Spastic hemiplegia and hemiparesis affecting dominant side • Spastic hemiplegia and hemiparesis affecting non-dominant side • Congenital Diplegia – Infantile hemiplegia • Infantile cerebral palsy, specified or unspecified • Disorders of eye movement (strabismus) • Laryngeal spasm • Achalasia and cardiospasm • Gustatory hyperhydrosis (Frey's syndrome) • Hemifacial spasms • Primary focal hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met: o The patient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and o Documentation that the patient has failed a 6-month trial of conservative management

	including the use of topical aluminum chloride or extra strength antiperspirant Botulinum Toxin Type B (Myobloc): Medicaid covers botulinum toxin type B (Myobloc) for the following condition: 1. Spasmodic Torticollis, secondary to cervical dystonia 3) Dosage Limitations for Botulinum Toxin Type A (Botox): the cumulative dosage should not exceed 600 units per 90 days. 4) Dosage l imitations for Botulinum Toxin Type B (Myobloc): 10,000 units per 12 weeks (three months).
03/26/2007	**Deletion:** 1) Patient must have a diagnosis of strabismus or blepharospasm associated with dystonia in patients 12 years or older OR 2) Cervical Dystonia
02/1/2008	Added EPSDT Provision
11/03/2008	Added coverage for Sialorrhea
11/07/2008	Added that Exemption Forms will not be accepted for these drugs.
05/01/2012	Added Dysport and Xeomin coverage criteria, generic names for all 4 toxins, coverage for upper limb spasticity in adults, coverage for chronic migraine, coverage for urinary incontinence, changed primary focal hyperhidrosis to severe axillary hyperhidrosis, updated off label uses
08/15/2014	Added coverage under Botox for overactive bladder
04/06/2017	Added coverage under Botox for lower limb spasticity in adults Added coverage under Dysport- upper limb spasticity in adults, lower limb spasticity in pediatrics age 2 and older Added coverage under Xeomin for upper limb spasticity in adults
03/21/2019	Change Dysport max dose to 1500u every 12 weeks

Wellcare of North Carolina **Effective Date: August 1, 2011**
Prior Authorization Criteria **Amended Date: November 21, 2019**
Opioid Dependence Therapy Agents

Therapeutic Class Code: H3W
Therapeutic Class Description: Opioid Dependence Therapy Agents

Medication
Suboxone® Film
Sublocade™
buprenorphine/naloxone tablets
buprenorphine/naloxone film
buprenorphine tablets
Zubsolv®
Bunavail®

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- that is unsafe, ineffective, or experimental/investigational.

- that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's

documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to
correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

Suboxone® Film (completion of prior approval form is not necessary)

- Prescription must be written by a prescriber who has an "X"DEA number[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid use is not occurring.
- Maximum daily dose of 16 mg/day (Suboxone and buprenorphine/naloxone). For daily doses between 16mg and up to 24mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

Sublocade® (completion of prior approval form is not necessary)

- Prescription must be written by a prescriber who has an "X"DEA number[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid use is not occurring.
- Beneficiary must have received treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days before using Sublocade.
- Maximum dose of two monthly initial doses of 300 mg followed by 100 mg monthly maintenance doses.

buprenorphine /naloxone tablets, buprenorphine /naloxone film, Zubsolv® and Bunavail® (requires trial and failure of Suboxone Film or a medical reason the beneficiary cannot use Suboxone Film)

- Prescription must be written by a prescriber who has an "X"DEA number[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid or use is not occurring.

- Maximum daily dose of 16 mg/day (buprenorphine/naloxone). For daily doses between 16mg and up to 24mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

- Maximum daily dose of 11.4 mg/day (Zubsolv). For daily doses between 11.4mg and up to 17.1mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

- Maximum daily dose of 8.4 mg/day (Bunavail). For daily doses between 8.1mg and up to 12.6mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

- Requests for combination products can be approved for up to 12 months.

buprenorphine (single ingredient products) (requires prior approval)

- Prescription must be written by a prescriber who has an "X"DEA number[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Beneficiary must be unable to take Suboxone Film®. Acceptable reasons include:
  - Beneficiaries who are pregnant or breast feeding. (Please provide documentation)
  - Allergy to naloxone which includes the following signs and symptoms: rashes, hives, pruritis, bronchospasm, angioeurotic edema and anaphylactic shock. (Documentation required)
- Requests for buphrenorphine (single ingredient) products may be approved for up to 12

months for beneficiaries with allergies to naloxone.

- Requests for buphrenorphine (single ingredient) products may be approved for up to 9 months during pregnancy and in 2 month increments thereafter during breast feeding.
- Maximum daily dose of 16 mg/day. For daily doses between 16mg and up to 24mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.
- Initial requests and renewals require documentation as to why the beneficiary cannot use a combination product.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid use is not occurring.[B]

References

1. Package Insert-Suboxone®, Subutex®, Reckitt Benckiser Pharmaceuticals, Inc., Richmond VA 23235.
2. Narcotic Agonist-Antagonist Analgesics. Drug Facts and Comparisons, Drug Facts and Comparisons, Wolters Kluwer Health. St. Louis (MO): updated monthly.
3. www.suboxone.com
4. Package Insert – Zubzolv® 2013 Orexo US, Inc. All rights reserved. Revised 7/2013
5. Package Insert- Bunavail ® June 2014 BioDelivery Science International, Inc. Raleigh, NCUSA 27607
6. Package Insert- Sublocade™ Revised January 2018 Indivior, Inc. North Chesterfield, VA

Criteria Change Log	
08/01/2011	Criteria effective date
06/15/2012	Added Suboxone® Film
08/15/2014	Added Zubsolve®
03/02/2015	Added Bunavail®
11/01/2017	Added criteria for single ingredient coverage for naloxone allergy or pregnancy/breastfeeding. Added Zubsolv® GCN. PA Criteria Name Changed from Buprenorphine and Buprenorphine/Naloxone to Opioid Dependence Therapy Agents Removed PA requirement on Suboxone Film®
06/05/2018	Changed Physician to Prescriber Add Sublocade™
10/01/2018	Maximum Dose Limits with Overrides
11/21/2019	Added generic buprenorphine /naloxone film

WellCare of North Carolina
Prior Authorization Criteria
PCSK9 Inhibitors

Effective Date: January 1, 2016
Revised Date: May 21, 2020

Therapeutic Class Code: M4T
Therapeutic Class Description: Antihyperlipidemic - PCSK9 Inhibitors

Medications
Praluent® (alirocumab)
Repatha™ (evolocumab)

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under

21 years of age does **NOT** eliminate the requirement for prior approval.

b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for all PCSK9 Inhibitors

- Beneficiary must be 18 years of age or older

AND

- Beneficiary is currently taking maximum dose atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®) for their age and has completed 90 days of treatment. **Provider must verify adherence through consultation with the beneficiary's pharmacy.**
  - Failure to reach target LDL-C (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for beneficiaries with clinical ASCVD and <100 mg /dL for beneficiaries with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD) after taking atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®) for 90 days.
  - For intolerance to atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®), trial and failure of both of these statins at lower dose must be utilized and documented.
    - Clinically significant intolerance or allergic reaction to statin treatment must be documented and attached to the prior authorization. Examples of significant intolerance includes severe muscle pain, significant liver abnormalities, and rhabdomyolysis. Intolerance does not include fatigue, cognitive impairment, or mild aches.

AND

  - Baseline LDL labs prior to any treatment and labs after previous treatments showing inadequate control on statins AND ezetimibe must be attached to the initial prior authorization request.

AND

- Beneficiary must continue both PCK9 Inhibitor and high dose atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®) to continue therapy unless otherwise approved due to intolerance.

Criteria for alirocumab (Praluent®)

- Beneficiary must have a diagnosis Heterozygous Familial Hyperchoesterolemia (HeFH)

  OR

- Beneficiary must have clinical atherosclerotic cardiovascular disease, defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin.

  OR

- Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C ≥ 190 mg/dL)

Criteria for evolocumab (Repatha®)

- Beneficiary must have a diagnosis Heterozygous (HeFH) or Homozygous Familial Hyperchoesterolemia (HoFH)
  - For patients with a diagnosis of HoFH, the age limit is 13 years and older.

  OR

- Beneficiary must have clinical atherosclerotic cardiovascular disease defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin.

  OR

- Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C ≥ 190 mg/dL)

References

1. Drug Effectiveness Review Project: Propoprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors Draft Original Report, May 2015, Kim Peterson, MS, Brittany Holzhammer, MPH, Marian McDonagh, PharmD
2. Drug Effectiveness Review Project: Propoprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors Draft Original Report-Appendixes and Evidence Tables, May 2015, Kim Peterson, MS, Brittany Holzhammer, MPH, Marian McDonagh, PharmD
3. Praluent® (alirocumab) package insert. ©2015 Regeneron Pharmaceuticals, Inc./ sanofi-aventis U.S. LLC. Updated April 2019.
4. Blom DJ, Hala T, Bolognese M, et al. A 52-week Placebo-Controlled Trial of Evolocumab in Hyperlipidemia. N Engl J Med 2014; 370:1809-19.
5. Repatha™ (evolocumab) package insert v2. ©2015 Amgen, Inc. updated 12/2017

Criteria Change Log

01/01/2016	Criteria effective date
06/12/2018	Added new GCN 41834
05/21/2020	Removed GCN's Updated links to EPSDT and Billing Guide Removed under 75 years of age Added: AND ezetimibe Removed: Beneficiary's LDL level is greater or equal to 130 mg/dl Added: Failure to reach target LDL-C (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for beneficiaries with clinical ASCVD and <100 mg /dL for beneficiaries with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD) For Praluent: Removed: such as heart attack or stroke Added: defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin. OR Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C ≥ 190 mg/dL For Repatha: Removed: such as heart attack or stroke Added: defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin. OR Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C ≥ 190mg/dL)

WellCare of North Carolina **Prior Authorization Criteria** **Relistor**	**Effective Date: September 27, 2020** **Amended Date:**

Therapeutic Class Code: H3Y
Therapeutic Class Description: Mu-Opioid Receptor Antagonists, Peripherally-Acting

Medication
Relistor syringe
Relistor tablet
Relistor vial

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure:

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to

correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Coverage of Relistor tablets:

a. Beneficiary has a diagnosis of opioid-induced constipation with chronic non-cancer pain (including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation);
b. Beneficiary is age 18 or older;
c. Beneficiary does not have known or suspected mechanical gastrointestinal obstruction;
d. Beneficiary has received opioids for at least 4 weeks duration;
e. Beneficiary has tried and failed or has contraindication, or intolerance to Amitiza AND Movantik; and
f. Initial approval shall be for up to 4 months.

Criteria for Coverage of Relistor vial/syringe:

a. Beneficiary has a diagnosis of opioid-induced constipation with one of the following:
    1. Chronic non-cancer pain (including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation)
    2. Advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care; and
b. Beneficiary is age 18 or older
c. Beneficiary does not have known or suspected mechanical gastrointestinal obstruction

d. Beneficiary has received opioids for at least 4 weeks duration
e. Beneficiary has tried and failed or has contraindication, or intolerance to Amitiza AND Movantik
f. Initial approval shall be for up to 4 months.

Criteria for Continuation of Coverage of Relistor:

a. All of the above criteria for initial coverage of Relistor are met.
b. Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
c. Reauthorization shall be for up to 12 months.

References

1. Prescriber Information- Relistor. Salix Pharmaceuticals. Bridgewater, NJ. Revised 11/2018.

WellCare of North Carolina **Prior Authorization Criteria** **Relistor**	**Effective Date: September 27, 2020** **Amended Date:**

Criteria Change Log	
09/27/2020	Criteria effective date

WellCare of North Carolina
Prior Authorization Criteria
Topical Antihistamines

Effective Date: Feb. 25, 2019

Therapeutic Class Code: L3P

Therapeutic Class Description: Dermatological Antipruritics-Antihistamines Topical

Medication	Generic Code Number(s)
Prudoxin 5% cream	21210
Zonalon 5% cream	21210
doxepin 5% cream	21210

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

WellCare of North Carolina **Effective Date: Feb. 25, 2019**
Prior Authorization Criteria
Topical Antihistamines

EPSDT and Prior Approval Requirements
EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaids-benefit-children-and-adolescents.

Indications: Indicated for the short-term management of moderate pruritus in adults with Atopic Dermatitis or Lichen Simplex Chronicus

Initial Criteria for Coverage:

1. Atopic Dermatitis:
    - Beneficiary must have had previous treatment with at least one other topical antihistamine **AND** at least two topical steroid creams
    - Length of therapy may be approved for up to 10 days.
    - Quantity limit of 45 grams per 90 days

2. Lichen Simplex Chronicus:
    - Beneficiary must have had previous treatment with at least two topical steroid creams
    - Length of therapy may be approved for up to 10 days.
    - Quantity limit of 45 grams per 90 days

Continuation of Coverage (renewal request) Criteria:

1. **Initial** criteria above must be met and documentation provided that indicates the beneficiary has benefited from therapy but remains at high risk
2. Minimum of 3 months have passed between prior uses
3. Length of therapy may be approved for up to 10 days
4. Quantity limit of 45 grams per 90 days

References

1. Prudoxin package insert, Prestium Pharma, Newtown, PA. updated June 2015
2. Zonalon package insert, Bioglan Pharma, Inc., Malvern, PA. updated March 2015

WellCare of North Carolina
Prior Authorization Criteria
Topical Antihistamines

Effective Date: Feb. 25, 2019

Criteria Change Log

02/25/2019	Criteria effective date

WellCare of North Carolina **Effective Date: December 8, 2009**
Prior Authorization Criteria **Amended Date: October 21, 2020**
Topical Anti-Inflammatory Medications

Therapeutic Class Code: Q5K, T0I
Therapeutic Class Description: Topical Anti-inflammatory Medications Calcineurin Inhibitors, Topical Anti-inflammatory Medications, Phosphodiesterase-4 (PDE4) Inhibitors

Medication
Elidel® pimecrolimus cream
Protopic® tacrolimus ointment
Eucrisa®

Criteria:

Elidel®, pimecrolimus cream, Protopic® 0.03%, and tacrolimus 0.03%:

- Beneficiary has tried and failed on at least one prescription topical corticosteroid and beneficiary is 2 years old or older.

OR

- Beneficiary has a documented adverse reaction or contraindication that precludes trial of one topical corticosteroid.

Eucrisa:

- Beneficiary has tried and failed on at least one prescription topical corticosteroid and beneficiary is 3 months of age or older.

OR

- Beneficiary has a documented adverse reaction or contraindication that precludes trial of one topical corticosteroid.

Protopic® 0.1%, tacrolimus 0.1%:

- Beneficiary has tried and failed on at least one prescription topical corticosteroid and beneficiary is 18 years old or older.

OR

- Beneficiary has a documented adverse reaction or contraindication that precludes trial of one topical corticosteroid.

Procedures:

- May be approved for up to 1 year.

References

1. Novartis Pharmaceuticals Corp., Elidel package insert. East Hanover, New Jersey 07936;May 2009.

2. Astellas Pharma US, INC. Protopic package insert. Deerfield, IL 60015-2548 ; June 2009.

3. Anacor Pharmaceuticals, INC., Eucrisa package insert. Palo Alto, California: December 2016.Updated March 2020.

WellCare of North Carolina **Effective Date: December 8, 2009**
Prior Authorization Criteria **Amended Date: October 21, 2020**
Topical Anti-Inflammatory Medications

Criteria Change Log

12/08/2009	Criteria effective date
06/13/2017	Add Eucrisa®
10/17/2017	Add Dupixent®
06/14/2019	Moved Dupixent® to the Monoclonal Antibody Criteria
06/14/2019	Added generic pimecrolimus, changed to try and fail one steroid instead of two, changed "patient" to "beneficiary".
10/21/2020	Updated age for Eucrisa from 2 years to 3 months or older Changed to try and failure of one prescription topical corticosteroid

WellCare of North Carolina
Prior Authorization Criteria
Topical Antifungal Agents

Effective Date: 11/01/11
Revised Date: 06/12/19

Therapeutic Class Code: Q5F
Therapeutic Class Description: Antifungal Agent

Medication	Generic Code Number(s)	NDC Number(s)
Vusion	26571	
miconazole/zinc/petrolatum ointment 0.25-15%	26571	

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.

b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider

documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:** https://medicaid.ncdhhs.gov/

EPSDT provider page: https://medicaid.ncdhhs.gov/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria

1. Require a trial of at least two different prescription products from the following list within the previous 60 days: nystatin cream, nystatin ointment, nystatin/triamcinolone cream, nystatin/triamcinolone ointment, or clotrimazole cream.
2. Beneficiary must be at least 4 weeks of age.
3. A quantity limit of 50 gm per 60 days prescription is in place.

Procedures

Length of therapy may be approved for up to 60 days.

References

1. Stiefel Laboratories, Inc. Vusion package insert. Coral Gables (FL): 2010 March.

Criteria Change Log

11/01/2011	Criteria effective date
06/15/2012	Combined NC Medicaid and NC Health Choice criteria into one (no changes to criteria)
06/12/2019	Add generic miconazole/zinc/petrolatum ointment 0.25-15% to criteria

WellCare of North Carolina
Prior Authorization Criteria
Topical Local Anesthetics

Effective Date: September 15,2010
Revised Date: November 19, 2020

Therapeutic Class Code: Q5H
Therapeutic Class Description: Topical Local Anesthetics

Medication
Lidoderm 5% Patch and generic lidocaine patch
ZTLido
Zilacaine Patch

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

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EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the

beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

- Patient diagnosed with Post-Herpetic Neuralgia.

OR

- Neuropathic pain with a previous documented trial and failure of at least two of the following drug categories: tri-cyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAID's or COXII's

OR

- Chronic musculo-skeletal pain (greater than 6 month in duration) with a previous documented trial and failure of at least two of the following drug categories: tri-cyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAID's or COXII's

AND

- Prescribed dose within the FDA recommended maximum amount of 3 patches per day and no more than 90 patches per month.

Procedures:

- New prescriptions will be limited to coverage of 1 box (30 patches) upon the first fill. Subsequent refills will be for up to a 34 day supply.
- Length of therapy may be approved for up to 12 months.

References

1. Local Anesthetics, Topical. Drug Facts and Comparisons, Drug Facts and Comparisons, Wolters Kluwer Health. St. Louis (MO): updated monthly.

2. Prescriber Information-Lidoderm Patch ® (lidocaine patch 5%), Endo Pharmaceuticals, Inc., Chadds Ford, Pennsylvania 19317. March 2010.

3. Gold Standard, Inc. Lidoderm. *Clinical Pharmacology* [database online]. Available at: http://www.clinicalpharmacology.com. Accessed April 12, 2011.

4. Jefferies, K. Treatment of Neuropathic Pain. Semin Neurol. 2010; 30(4):425-432. http://www.medscape.com/viewarticle/730671 Accessed April 12, 2011.

5. Attal, N et al. EFNS guidelines on the pharmacological treatment of neuropathic pain: 2010 revision. European Journal of Neurology 2010; 17: 1113-1123.

6. Dworkin, RH et al. Pharmacologic management of neuropathic pain: evidence-based recommendations. Pain 2007 Dec 5; 132 (3):237-51.

7. Argoff, Charles E. et al. Consensus Guidelines: Assessment, Diagnosis, and Treatment of Diabetic Peripheral Neuropathic Pain. Mayo Clinic Proceedings April 2006; 81 (4 suppl): S1-S25.

8. Prescriber Information- ZTLido™ Scilex Pharmaceuticals, Inc.,San Diego, CA, 92121. Nov. 2018.

9. Prescriber Information- Zilacaine™ Actavis Laboratories UT, Inc. Salt Lake City, UT 84108. June 2018.

10. Product Information- LidoPure. Actavis Laboratories UT, Inc.Salt Lake City, UT 84108. February 2016.

Criteria Change Log

09/15/2010	Criteria effective date
09/18/2011	Added coverage for neuropathic pain and chronic musculo-skeletal pain
06/15/2012	Combined NC Health Choice and Medicaid coverage criteria
02/26/2019	Added generic lidocaine patch
06/19/2019	Added ZTLido
11/19/2019	Added LidoPure and Zilacaine
11/19/2020	Removed LidoPure

Wellcare of North Carolina **Effective Date: May 1, 2017**
Prior Authorization Criteria **Amended Date: March 1, 2021**
Agents for Duchenne Muscular Dystrophy

Therapeutic Class Code: Z1R
Therapeutic Class Description: GENETIC D/O TX-EXON SKIPPING ANTISENSE OLIGONUCLEOTIDE

Medication
Exondys 51
Viltepso
Vyondys 53

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

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EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of

Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

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EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage for Exondys 51:

- The beneficiary has a diagnosis of Duchenne Muscular Dystrophy;
  AND
- Medical records are submitted (ex: chart notes, laboratory values) that confirm the mutation of the Duchenne Muscular Dystrophy gene is amenable to exon 51 skipping;
  AND
- Medication is prescribed by or in consultation with a neurologist;
  AND
- The beneficiary retains meaningful voluntary motor function (beneficiary is able to speak, manipulate objects using upper extremities, ambulate, etc.);
  AND
- The beneficiary has been assessed for any physical therapy and/or occupational therapy needs;
  AND
- Baseline documentation of ≥ 1 of the following:
  - Dystrophin level
  - 6-minute walk test (6WMT) or other timed function tests
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) % predicted
  - Performance of Upper Limb (PUL);

  AND
- The beneficiary is not taking Exondys 51 with any other RNA antisense agent, or any other gene therapy;
  AND
- Exondys 51 dosing for Duchenne Muscular Dystrophy is in accordance with the USFDA

- approved labeling: maximum dosing of 30mg/kg once weekly;
  AND
- Maximum length of initial approval: 6 months

Criteria for Initial Coverage for Vyondys 53:

- The beneficiary has a diagnosis of Duchenne Muscular Dystrophy;
  AND
- Medical records are submitted (ex: chart notes, laboratory values) that confirm the mutation of the Duchenne Muscular Dystrophy gene is amenable to exon 53 skipping;
  AND
- Medication is prescribed by or in consultation with a neurologist;
  AND
- The beneficiary retains meaningful voluntary motor function (beneficiary is able to speak, manipulate objects using upper extremities, ambulate, etc.);
  AND
- The beneficiary has been assessed for any physical therapy and/or occupational therapy needs;
  AND
- Baseline documentation of ≥ 1 of the following:
  - Dystrophin level
  - 6-minute walk test (6WMT) or other timed function tests
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) % predicted;
  - Performance of Upper Limb (PUL);

  AND

- The beneficiary is not taking Vyondys 53 with any other RNA antisense agent, or any other gene therapy;
  AND
- Vyondys 53 dosing for Duchenne Muscular Dystrophy is in accordance with the USFDA approved labeling: maximum dosing of 30mg/kg once weekly;
  AND
- Maximum length of initial approval: 6 months

Criteria for Initial Coverage for Viltepso

- The beneficiary has a diagnosis of Duchenne Muscular Dystrophy;
  AND
- Medical records are submitted (ex chart notes, laboratory values) demonstrating a mutation on the DMD gene that is amenable to exon 53 skipping;
  AND
- Medication is prescribed by or in consultation with a neurologist;
  AND
- The beneficiary retains meaningful voluntary motor function (e.g. beneficiary is able to speak, manipulate objects using upper extremities, ambulate);
  AND
- The beneficiary has been assessed for any physical therapy and/or occupational therapy needs;
  AND

- The beneficiary is not on concomitant therapy with other DMD-directed antisense oligonucleotides
- (e.g., eteplirsen, golodirsen);
  AND
- The beneficiary's serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio has been measured prior to the start of therapy;
  AND
- Prescriber attestation that serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio will be measured and during treatment (monthly urine dipstick with serum cystatin C and urine protein-to-creatinine ratio every 3 months);
  AND
- Baseline documentation of ≥ 1 of the following:
  - Dystrophin level; **OR**
  - 6-minute walk test (6MWT) or other timed function tests; **OR**
  - Upper limb function (ULM) test; **OR**
  - North Star Ambulatory Assessment (NSAA); **OR**
  - Forced Vital Capacity (FVC) percent predicted
  - Performance of Upper Limb (PUL);
- Maximum length of initial approval: 6 months

Criteria for Renewal of Coverage

- The beneficiary must continue to meet initial approval criteria;
  AND
- The beneficiary has demonstrated a response to therapy compared to pretreatment baseline in of ≥ 1 of the following (not all-inclusive):
  - Increase in dystrophin level; **OR**
  - Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests; **OR**
  - Stability, improvement, or slowed rate of decline in ULM test; **OR**
  - Stability, improvement, or slowed rate of decline in NSAA; **OR**
  - Stability, improvement, or slowed rate of decline in FVC% predicted; **OR**
  - Improvement in quality of life;

  AND
- The beneficiary has not experienced any treatment-restricting adverse effects (e.g. renal toxicities, proteinuria);
- Maximum length of renewal approval: 6 months

References

1. Prescriber Information Exondys 51 ® (eteplirsen) Sarepta Therapeutics, Inc, Cambridge, MA 02142. September 2016.
2. Vyondys 53 [package insert]. Cambridge, MA. Sarepta Therapeutics, Inc. December 2019.
3. Viltepso [package insert]. Paramus, NJ; NS Pharma; August 2020.

Criteria Change Log

05/01/2017	Criteria effective date
03/01/2021	Vyondys 53 added Viltepso

WellCare of North Carolina
Prior Authorization Criteria
Epidiolex

Effective Date: February 1, 2021

Therapeutic Class Code: H4E
Therapeutic Class Description: Anticonvulsant - Cannabinoid Type

Medication
Epidiolex

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

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EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
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ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

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EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Critieria for Coverage of Epidiolex

Initial Criteria for Coverage

- Beneficiary must be ≥ 2 years of age.

  AND
- Beneficiary has seizures associated with Lennox-Gastaut syndrome (LGS) OR Dravet syndrome (DS).

  AND
- Prescriber to provide attestation that beneficiary's baseline serum transaminases (ALT and AST) and total bilirubin levels have been completed.

  AND
- Prescriber to provide attestation that beneficiary is not currently using recreational or medicinal cannabis along with this product.

  AND
- Prescriber to provide attestation that beneficiary has refractory epilepsy (beneficiary has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]).

  AND
- Prescriber to provide attestation that Epidiolex will be used in adjunct to ≥ 1 antiepileptic drug.

Continuation of Coverage (renewal request)

- Beneficiary continues to meet above criteria.

  AND

- Prescriber to provide attestation to monitoring beneficiary's annual serum transaminases (ALT and AST) and total bilirubin levels.

References

1. Epidiolex [package insert]. Carlsbad, CA; Greenwich Biosciences; June 2018.

WellCare of North Carolina **Effective Date: February 1, 2021**
Prior Authorization Criteria
Epidiolex

Criteria Change Log

02/01/2021	Criteria effective date

Wellcare of North Carolina **Effective Date: January 25, 2021**
Prior Authorization Criteria
Gattex

Therapeutic Class Code: D6I
Therapeutic Class Description: SBS- Glucagon-Like Peptide-2 Analogs

Medication
Gattex

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

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EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21

Years of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage of Gattex:

- Beneficiary is ≥ 1 year of age; AND
- Beneficiary has diagnosis of short bowel syndrome, AND
- Beneficiary has been dependent on parenteral nutrition for at least 12 months; AND
- Beneficiary is receiving parenteral nutrition at least 3 times weekly

Criteria for Continuation of Coverage of Gattex:

- Beneficiary is continuing to receive parenteral nutrition while taking the requested agent

References

1. Gattex [package insert]. Lexington, MA; Shire-NPS; May 2019.

Wellcare of North Carolina **Effective Date: January 25, 2021**
Prior Authorization Criteria
Gattex

Criteria Change Log

01/25/2021	Criteria effective date

WellCare of North Carolina
Prior Authorization Criteria
Zolgensma

Effective Date: January 25, 2021

Therapeutic Class Code: Z0K
Therapeutic Class Description: Gene Therapy Agents - SMN Protein Deficiency

Medication
Zolgensma Kit

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
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ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in

c. the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Coverage:

1. Diagnosis of SMA with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. (please attach documentation)
2. Genetic testing confirms the presence of one of the following (a, b, or c): (please attach documentation)
   a. Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);
   b. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7);
   c. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2));
3. Prescribed by or in consultation with a neurologist;
4. Age < 2 years;
5. Documentation of one of the following baseline scores (a or b): (please attach documentation)
   a. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score;
   b. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score;
6. Documentation of both of the following (a and b): (please attach documentation)
   a. Baseline laboratory tests demonstrating Anti-AAV9 antibody titers ≤ 1:50 as determined by ELISA binding immunoassay;
   b. Baseline liver function test, platelet counts, and troponin-I;
7. Beneficiary does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence, tracheostomy, non-invasive ventilation beyond the use for sleep); (please attach documentation)
8. Beneficiary has not been previously treated with Zolgensma;
9. Zolgensma is not prescribed concurrently with Spinraza®;
10. Member does not have an active viral infection

11. Total dose does not exceed 1.1×10^{14} vector genomes (vg) per kilogram (kg) body weight
12. Zolgensma must be given in conjunction with pre and post infusion parenteral corticosteroids.

Approval duration: 4 weeks (one-time infusion per lifetime)

References

1. Zolgensma Prescribing Information, AveXis, Inc., Bannockburn, IL., 2019.

Criteria Change Log

01/25/2021	Criteria effective date

WellCare of North Carolina **Effective Date: August 15, 2014**
Prior Authorization Criteria **Amended Date: November 17, 2020**
Hepatitis C Virus Medications

Therapeutic Class Code: W5Y, W0B, W0D, W0A, W0E, W0G
Therapeutic Class Description: Hepatitis C Virus nucleotide analog NS5B RNA Dependent Polymerase Inhibitor, Hepatitis C Virus NS3/4A Serine Protease Inhibitor, and Hepatitis C Virus NS5A Inhibitor and Nucleotide Analog NS5B Polymerase Inhibitor, NS5A, NS3/4A Protease, Nucleotide NS5B Polymerase Inhibitor Combination

Medication
Mavyret™ (glecaprevir and pibrentasvir)
Epclusa® (sofosbuvir and velpatasvir) and generic sofosbuvir and velpatasvir
Harvoni® 90-400mg tablet (ledipasvir and sofosbuvir) and generic ledipasvir and sofosbuvir
Harvoni® pellet packs
Sovaldi® 400mg tablet (sofosbuvir)
Sovaldi® pellet packs
Viekira Pak™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir)
Vosevi™ (sofosbuvir/Velpatasvir/Voxilaprevir)
Zepatier® (elbasvir and grazoprevir)

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.
EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

A. Criteria for Coverage of Sovaldi® (sofosbuvir):

Covered for the following conditions:

1. Beneficiary has a diagnosis of chronic hepatitis C infections with confirmed genotype:
   a. Genotype 1 or 4 without cirrhosis or with compensated cirrhosis **AND** Beneficiary is 18 years or older **OR**
   b. Genotype 2 or 3 without cirrhosis or with compensated cirrhosis **AND** Beneficiary is 3 years of age or older **OR**
   c. Beneficiary has CHC infection with hepatocellular carcinoma awaiting liver transplant.
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable;
   AND
3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;

AND

4. Beneficiaries must agree to toxicology and/or alcohol screens as needed;
   AND
5. The provider must be reasonably certain that treatment will improve the beneficiary's overall health status;
   AND
6. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs;
   AND
7. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin and pegylated interferon alfa for genotypes 1 and 4;
   OR
8. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin for beneficiaries with genotype 1 who are peginterferon-ineligible (medical record documentation of previous peginterferon therapy or reason for ineligibility must be submitted for review);
   OR
9. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin for genotypes 2 and 3 and/or in CHC beneficiaries with hepatocellular carcinoma awaiting liver transplant.

Approval limits for sofosbuvir (Sovaldi) for all beneficiaries meeting criteria will be as follows:

	Adult Patient Population	**Regimen and Duration**
Genotype 1 or 4	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + peginterferon alfa + ribavirin 12 weeks
Genotype 1	PEG-interferon ineligible	SOVALDI +ribavirin 24 weeks
Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis	SOVALDI + Ribavirin 24 weeks
Genotype 3	Treatment-naïve and treatment-experienced with compensated cirrhosis (Child-Pugh A)	SOVALDI + Ribavirin 24 weeks
Genotype 1,2, 3, or 4	Diagnosis of hepatocellular carcinoma awaiting liver transplantation	SOVALDI +ribavirin up to 48 weeks or until liver transplantation whichever comes first

	Pediatric Patient Population 3 Years of Age and Older	**Regimen and Duration**
Genotype 2	Treatment-naïve and treatment- experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment- experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 24 weeks

For initial authorization of Sovaldi® (sofosbuvir) approval will be limited to an 8 week maximum.

For reauthorization/completion of Sovaldi® (sofosbuvir):

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;

AND

- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;

AND

- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Sofosbuvir (Sovaldi®) is being used as monotherapy;
  OR
- Sofosbuvir (Sovaldi®) is being used with any other sofosbuvir containing regimen;
  OR
- Beneficiary has FDA labeled contraindications to sofosbuvir (Sovaldi®);
  OR
- Beneficiary is pregnant;
  OR
- Beneficiary has severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or requires dialysis (AASLD/IDSA 2014);
  OR
- Beneficiary is a non-responder to sofosbuvir;
  OR
- Beneficiary has previously failed therapy with a treatment regimen that included (sofosbuvir);
  OR
- Beneficiary has hepatocellular carcinoma and is not awaiting liver transplant.

B. Criteria for Coverage of Harvoni® (ledipasvir/sofosbuvir) and generic ledipasvir/sofobuvir:

Covered for the following conditions:

1. Beneficiary is 3 years of age or older with a diagnosis of hepatitis C (CHC) with
   a. genotype 1,4,5,6 infection without cirrhosis or with compensated cirrhosis;
   OR
   b. genotype 1 infection with decompensated cirrhosis, in combination with ribavirin;
   OR
   c. genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin;
   AND
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable;
   AND
3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;
   AND
4. Beneficiaries must agree to toxicology and/or alcohol screens as needed;
   AND
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status;
   AND
6. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs.

Approval limits for Harvoni® and generic ledipasvir/sofosbuvir for all beneficiaries 3 years of age and older with Genotype 1,4,5, or 6 meeting criteria will be as follows:

	Patient Population	**Regimen and Duration**
Genotype 1	Treatment-naïve without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL	HARVONI 8 Weeks
	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks
	Treatment-experienced without cirrhosis	HARVONI 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks
	Treatment-naïve and treatment-experienced with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 weeks

	Patient Population	Regimen and Duration
Genotype 4, 5, or 6	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks

For initial authorization of Harvoni® (ledipasvir/sofosbuvir) and generic ledipasvir/sofosbuvir approval will be limited to an 8 week maximum for 8, 12 or 24 week regimens

For reauthorization/completion of Harvoni, (ledipasvir/sofosbuvir) and generic ledipasvir/sofosbuvir:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;
  AND
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;
  AND
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Harvoni® or generic ledipasvir/sofosbuvir;
  OR
- Harvoni® or generic ledipasvir/sofosbuvir is being used in combination with other drugs containing sofosbuvir.

C. Criteria for Coverage of Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets & dasabuvir tablets):

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1b without cirrhosis or with compensated cirrhosis or confirmed genotype 1a without cirrhosis or with compensated cirrhosis in combination with ribavirin;
   AND
2. Treatment includes use of ribavirin for all treatment courses **EXCEPT** for genotype 1b;
   AND
3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable;
   AND
4. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;
   AND

5. Beneficiaries must agree to toxicology and/or alcohol screens as needed;
   AND
6. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status;
   AND
7. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs;
   AND
8. Prior to initiation of VIEKIRA PAK™ the provider has assessed for laboratory and clinical evidence of hepatic decompensation;
   AND
9. For beneficiaries with cirrhosis:
   a. Provider is monitoring for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage); **and**
   b. Provider is performing hepatic laboratory testing, including direct bilirubin levels, at baseline and during the first four weeks of starting treatment and as clinically indicated.

Approval limits for Viekira™ Pak for all beneficiaries meeting criteria will be as follows:

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	VIEKIRA PAK + ribavirin	12 weeks
Genotype 1a, with compensated cirrhosis	VIEKIRA PAK + ribavirin	24 weeks **
Genotype 1b, with cirrhosis	VIEKIRA PAK	12 weeks

*Note: Follow the genotype 1a dosing recommendations in beneficiaries with an unknown genotype 1 subtype or with mixed genotype 1 infection

** Viekira Pak administered with ribavirin for 12 weeks may be considered for some beneficiaries based on prior treatment history

- HCV/HIV-1 co-infection: For beneficiaries with HCV/HIV-1 co-infection, follow dosage recommendations in the table above.
- Liver Transplant Recipients: In liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis < or = 2), the recommended duration of Viekira Pak with ribavirin is 24 weeks.

For initial authorization of Viekira Pak™ approval will be limited to an 8 week maximum for 12 or 24 week regimens.

For reauthorization/completion of Viekira Pak™

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;
  AND
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;
  AND
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing

for compliance).

Exclusions to coverage:

- Viekira Pak™ is being used in combination with other protease inhibitors used to treat CHC (i.e. boceprevir, simeprevir, or telaprevir) or in combination with another nucleotide NS5B polymerase inhibitor such as Sovaldi® (sofosbuvir);
  OR
- Beneficiary is using Viekira Pak™ in combination with another NS5A inhibitor;
  OR
- Beneficiary is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of sofosbuvir;
  OR
- Beneficiary is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of ledipasvir;
  OR
- Beneficiary has decompensated liver disease as defined by Child-Pugh classification score of Child Class B or C (VIEKIRA PAK™ is contraindicated in beneficiaries with moderate to severe hepatic impairment (Child-Pugh B and C);
  OR
- Beneficiary has attempted a previous course of therapy with Viekira Pak™;
  OR
- Beneficiary has FDA labeled contraindications to Viekira Pak™.

D. Criteria for Coverage of Zepatier (elbasvir and grazoprevir):

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1 or genotype 4;
   AND
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable;
   AND
3. Beneficiaries with Genotype 1a baseline NS5A polymorphisms, Genotype 1a or 1b who are treatment experienced with Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor or Genotype 4 who are treatment experienced with Peginterferon alfa + ribavirin, Zepatier must be prescribed with ribavirin;
   AND
4. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;
   AND
5. Beneficiaries must agree to toxicology and/or alcohol screens as needed;
   AND
6. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status;
   AND
7. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow -up appointments and labs.

Approval limits for Zepatier® for all beneficiaries meeting criteria will be as follows:

Beneficiary Status	Treatment	Total Approval Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced* **without** baseline NS5A polymorphisms†	ZEPATIER	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV- experienced* **with** baseline NS5A polymorphisms†	ZEPATIER + Ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced*	ZEPATIER	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced‡	ZEPATIER + Ribavirin	12 weeks
Genotype 4: Treatment-naïve	ZEPATIER	12 weeks
Genotype 4: PegIFN/RBV-experienced*	ZEPATIER + Ribavirin	16 weeks

*Peginterferon alfa + ribavirin.
†Polymorphisms at amino acid positions 28, 30, 31, or 93.
‡Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.
Genotype 1a: Testing for the presence of virus with NS5A resistance-associated polymorphisms is recommended

For initial authorization of Zepatier®, approval will be limited to an 8 week maximum for 12 or 16 week regimens.

For reauthorization/completion of Zepatier®:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;
  AND
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;
  AND
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Zepatier®;
  OR
- Beneficiary has moderate to severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation;
  OR
- Zepatier® is being co administered with organic anion transporting polypeptides 1B1/3 (OATP1B1/3)

inhibitors, strong inducers of cytochrome P450 3A (CYP3A), or efavirenz.

F. Criteria for Coverage of Epclusa® (velpatasvir/sofosbuvir) and generic velpatasvir/sofosbuvir:

Covered for the following conditions:

1. Beneficiary is 6 years if age or older weighing at least 17kg with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1, 2, 3, 4, 5 or genotype 6 without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin;
   AND
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable;
   AND
3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;
   AND
4. Beneficiaries must agree to toxicology and/or alcohol screens as needed;
   AND
5. Provider must be reasonably certain that the treatment will improve the beneficiary's overall health status;
   AND
6. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs.

Approval limits for Epclusa® and generic velpatasvir/sofosbuvir for all beneficiaries meeting criteria will be as follows:

Patient Population	**Treatment Duration**
Genotypes 1,2,3,4,5, or 6 treatment -naïve and treatment -experienced[a] without cirrhosis and with compensated cirrhosis (Child Pugh A)	Epclusa and generic velpatasvir/sofosbuvir for 12 weeks
Genotypes 1,2,3,4,5, or 6 treatment- naïve and treatment -experienced[a] with decompensated cirrhosis (Child-Pugh B and C)	Epclusa and generic velpatasvir/sofosbuvir + ribavirin for 12 weeks
For treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Epclusa and generic velpatasvir/sofosbuvir 12 weeks

[a.] In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

- HCV/HIV-1 coinfection: For beneficiaries with HCV/HIV-1 coinfection, follow the dosage recommendations in the table above.

For initial authorization of Epclusa® (velpatasvir/sofosbuvir) and generic velpatasvir/sofosbuvir approval will be limited to an 8 week maximum.

For reauthorization/completion of Epclusa®, (velpatasvir/sofosbuvir) and generic

velpatasvir/sofosbuvir:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;
  AND
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;
  AND
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Epclusa® or generic velpatasvir/sofosbuvir;
  OR
- Epclusa® or generic velpatasvir/sofosbuvir is being used in combination with other drugs containing sofosbuvir.

G. Criteria for Coverage of Mavyret™ (glecaprevir and pibrentasvir)

Covered for the following conditions:

1. Beneficiary is 12 years old or older or weighing at least 45 kg with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1,2,3,4,5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A);
   AND
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable;
   AND
3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;
   AND
4. Beneficiaries must agree to toxicology and/or alcohol screens as needed;
   AND
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status;

Mavyret™
Recommended Duration for Treatment-Naïve Patients

HCV Genotype	Treatment Duration	
	No Cirrhosis	Compensated Cirrhosis (Child Pugh-A)
1,2,3,4,5, or 6	8 weeks	8 weeks

Liver or kidney transplant recipients: 12 weeks

Mavyret™
Recommended Duration for Treatment-Experienced Patients

		Treatment Duration	
HCV Genotype	Patients Previously Treated with a Regimen Containing:	No Cirrhosis	Compensated Cirrhosis (Child Pugh A)
1	An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI[2] without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1,2,4,5, or 6	PRS[3]	8 weeks	12 weeks
3	PRS[3]	16 weeks	16 weeks

1. In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
2. In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.
3.PRS=Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

For initial authorization of Mavyret ™ approval will be limited to an 8 week maximum. (for all beneficiaries)

For reauthorization/completion of Mavyret™ (for beneficiaries requiring greater than 8 weeks of therapy)

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;
  AND
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;
  AND
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Mavyret®;
  OR
- Mavyret is being used in combination with atazanavir and rifampin;
  OR
- Beneficiary has moderate-severe hepatic impairment (Child-Pugh B or C;)

OR

- Beneficiary has any history of prior hepatic decompensation;
  OR
- Beneficiary has been previously treated with regimens containing BOTH a NS5A inhibitor and aNS3/4A protease inhibitor.

H. Criteria for Coverage of Vosevi™

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1, 2, 3, 4, 5 or genotype 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A);
   AND
2. Beneficiary has previously been treated with an HCV regimen containing an NS5A inhibitor (genotype 1,2,3,4,5, or 6) or has previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor (genotype 1a or genotype 3);
   AND
3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable
   AND
4. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request;
   AND
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status;
   AND
6. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs.

Approval limits for Vosevi ™ all beneficiaries meeting criteria will be as follows:

Genotype	Beneficiaries previously treated with an HCV Regimen Containing:	Vosevi Duration
1,2,3,4,5, or 6	An NS5A inhibitor[a]	12 weeks
1a or 3	Sofosbuvir without an NS5A inhibitor[b]	12 weeks

a. In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.
b. In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhib
itor (boceprevir, simeprevir or telaprevir).

For initial authorization of Vosevi™ approval will be limited to an 8 week maximum

For reauthorization/completion of Vosevi™:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted;
  AND
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews;
  AND
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Vosevi™;

Scoring System Charts:
Compensated Liver Disease

Child Pugh Classification (AASLD/IDSA 2014)

Parameters			
Points Assigned	1 point	2 points	3 points
Total Bilirubin	<34	34-50	>50
Serum Albumin	>35	28-35	<28
Prothrombin Time/INR	INR<1.7	1.71-2.30	>2.30
Ascites	None	Mild	Moderate to Severe
Hepatic Encephalopathy	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)

Grade	Points	One-year patient survival (%)	Two-year patient survival (%)
A: well-compensated disease	5-6	100	85
B: significant functional compromise	7-9	80	60
C: decompensated disease	10-15	45	35

Scoring Systems for Fibrosis Staging (AASLD 2009)

Stage (F)	**IASL (The International Association for the Study of Liver)**	**Batts-Ludwig**	**Metavir**
0	No fibrosis	No fibrosis	No fibrosis
1	Mild fibrosis	Fibrosis portal expansion	Periportal fibrotic expansion

2	Moderate fibrosis	Rare bridges or septae	Periportal septae 1 (septum)
3	Severe fibrosis	Numerous bridges or septae	Porto-central septae
4	Cirrhosis	Cirrhosis	Cirrhosis

Stage (F)	**Ishak**
0	No fibrosis
1	Fibrosis expansion of some portal areas with or without short fibrous septae
2	Fibrosis expansion of most portal areas with or without short fibrous septae
3	Fibrosis expansion of most portal areas with occasional portal to portal bridging
4	Fibrosis expansion of most portal areas with marked bridging (portal to portal and portal to central)
5	Marked bridging (portal to portal and portal to central) with occasional nodules (incomplete cirrhosis)
6	Cirrhosis

References:

1. Prescriber Information-Sovaldi ® (sofosbuvir) Gilead Sciences, Inc. Foster, City California 94404. December 2013. Revised August 2019.

2. Sofosbuvir for the Treatment of Hepatitis C and Evaluation of the 2014 American Association for the Study of Liver Diseases Treatment Guidelines, Allison Leof, PhD; Martha Gerrity, MD, MPH, PhD; Aasta Thielke, MPH; Valerie King, MD, MPH - Center for Evidence---based Policy Oregon Health & Science University, 3455 SW US Veterans Hospital Road, Mailstop SN---4N, Portland, OR 97239-2941.

3. Prescriber Information- Harvoni ® (ledipasvir/sofosbuvir) Gilead Sciences, Inc. Foster City, California 94404. October 2014. Revised August 2019.

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5. Prescriber Information – Viekira Pak™ (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) AbbVie, Inc. North Chicago, Illinois 60064. July 2018.
6. Prescriber Information- Daklinza™ (declatasvir) Bristol-Myers Squibb Company, Princeton, NJ 08543, USA. November 2017
7. FDA Safety Announcement. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm. Accessed October 23, 2015.
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September 9, 2019.

9. Prescriber Information- Zepatier® (elbasvir and grazoprevir) Merck and Co., Inc. Whitehouse Station, NJ 08889. USA. June 2018.
10. Prescriber Information- Epclusa® (velpatasvir/sofosbuvir) Gilead Sciences, Inc. Foster City, CA 94404. USA. November 2017. Updated March 2020.
11. Prescriber Information- Mavyret™ (glecaprevir and pibrentasvir)AbbVie, Inc. North Chicago, Illinois 60064. June 2019.
12. Prescriber Information- Vosevi™ (Sofosbuvir/Velpatasvir/Voxilaprevir) Gilead Sciences, Inc. Foster City, California 94404. November 2017.

Criteria Change Log

08/15/2014	Criteria effective date (Sovaldi® and Olysio® were in separate criteria)
01/22/2015	Combined Hepatitis C meds together and added coverage criteria for Harvoni®
03/23/2015	Added Viekira™ coverage criteria
03/14/2016	Added Daklinza™ and Technivie™ coverage criteria
05/18/2016	Added Zepatier® coverage criteria
02/07/2017	Added Epclusa® and Viekira XR™ coverage criteria
08/31/2017	Added dosing for pediatrics-Harvoni® and Sovaldi®.
11/01/2017	Removed requirements for fibrosis score
11/01/2017	Added criteria for coverage Mavyret™ and Vosevi™
04/21/2020	-Remove Olysio, -Add generic for Epclusa -Remove Viekira XR, -Add generic for Harvoni -Remove under Sovaldi criteria statement #11 that states beneficiary must have a clinical reason why they cannot use Harvoni before using Olysio with Sovaldi -Remove Beneficiary is 12 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1, 4, 5, or 6 -Add Adults with a diagnosis of hepatitis C (CHC) with genotype 1,4,5,6 infection without cirrhosis or with compensated cirrhosis OR Adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin OR Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin Pediatric beneficiaries 12 years of age or older or weighing at least 35 kg with genotype 1,4,5,or 6 without cirrhosis or with compensated cirrhosis -Add pediatric regimen and duration for Harvoni -Remove contraindicated/interaction charts throughout the criteria -change age of Mavyret to 12 and older or weighing at least 45 kg -clarified age ranges for Sovaldi -clarified Viekira Pak dosing chart -removed GCN for Daklinza 90 because termed -remove Technivie- termed -Epclusa clarified without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin. -Vosevi clarified genotypes

04/21/2020	Remove GCN's Sovaldi- add coverage criteria genotype 1 or 3 with decompensated cirrhosis or post-liver transplant in combination with daclatasvir and ribavirin lower minimum age from 12 years old to 3 years old Harvoni- lower age to 3 years of age add exclusion to coverage for severe renal impairment (CrCl less than 30mL/min, end stage renal disease, or on dialysis Viekira- remove dialysis as exclusion for coverage Daklinza- add decompensated cirrhosis or post-transplant beneficiaries Daklinza™ must be prescribed concomitantly with ribavirin remove exclusion to coverage for beneficiaries on dialysis remove exclusion to coverage for beneficiaries with decompensated liver disease (Child Pugh B or C) Zepatier- add coverage for beneficiaries with Genotyple 1a baseline NS5A polymorphisms, Genotype 1a or 1b who are treatment experienced with Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor or Genotype 4 who are treatment experienced with Peginterferon alfa + ribavirin Mavyret- add exclusions to coverage for beneficiaries with FDA labeled contraindications to Mavyret®; or if Mavyret is being used in combination with atazanavir and rifampin; or if beneficiary has severe hepatic impairment (Child-Pugh C); or if beneficiary has been previously treated with regimens containing BOTH a NS5A inhibitor and a NS3/4A protease inhibitor added dosing for liver and kidney transplant recipients All Hep C- Remove requirement for provider submitting a completed Beneficiary Readiness Form, however, provider does attest that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs. Remove exclusion to coverage for severe renal impairment (CrCl less than 30mL/min, end stage renal disease, or on dialysis Add those with history of prior decompensation as exclusion for coverage of Zepatier

11/17/2020	-Updated age for Epclusa to 6 & older or weighing at least 17 kg -Removed Daklinza -Ribavirin not required in combination with Viekira for genotype 1b -Removed drug interactions with amiodarone as exclusions -Add Harvoni pellet packs -Add Sovaldi pellet packs -Removed requirement for beneficiaries with history in the last year of alcohol abuse to be in a treatment program -Updated chart for Epclusa for transplant recipients

WellCare of North Carolina
Prior Authorization Criteria
Opioid Analgesics

Effective Date: March 4, 2002
Amended Date: March 1, 2021

Therapeutic Class Code: H3A,H3N
Therapeutic Class Description: Analgesics, Opioids; Analgesics, Opioid Agonist, NSAID Combination

Medication (Short Acting)
Abstral
Actiq and generic fentanyl citrate lozenges
Apadaz tablet and generic benzhydrocodone-acetaminophen tablet
Ascomp
butalbital-caffeine-acetaminophen with codeine
butorphanol spray
Capital with codeine suspension
Codeine sulfate
Demerol and generic meperidine
dihydrocodeine-acetaminophen-caffeine
Dilaudid and generic hydromorphone
Dsuvia
Fentora
Fiorinal with codeine and generic butalbital compound with codeine
hydrocodone/acetaminophen
hydrocodone/ibuprofen
Ibudone and generic hydrocodone/ibuprofen
Lazanda
Lorcet and generic hydrocodone/acetaminophen
Lortab and generic hydrocodone/acetaminophen
Levorphanol
morphine
Nalocet
Norco and generic hydrocodone/acetaminophen
Nucynta

Opana and generic oxymorphone
Oxaydo
oxycodone
oxycodone/acetaminophen
oxycodone/aspirin
oxycodone/ibuprofen
pentazocine-naloxone
Percocet and generic oxycodone/acetaminophen
PrimLev
Roxybond
Roxicodone and generic oxycodone
Subsys
Tylenol with codeine and generic acetaminophen with codeine
Ultracet and generic acetaminophen with tramadol
Ultram and generic tramadol
Vicodin and generic hydrocodone/acetaminophen
Xylon and generic hydrocodone/ibuprofen

Medication (Long Acting)
Arymo ER
Belbuca
Butrans and generic buprenorphine patch
Conzip and generic tramadol ER capsule
Dolophine and generic methadone
Duragesic and generic fentanyl
Embeda
Exalgo and generic hydromorphone ER
Hysingla ER
Kadian and generic morphine sulfate ER
MS Contin and generic morphine sulfate ER

MorphaBond ER
morphine sulfate ER
Nucynta ER
Oxycontin and generic oxycodone ER
oxymorphone ER
tramadol ER
Xtampza ER
Zohydro ER Capsules and generic hydrocodone ER

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21

Years of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination(includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Exemptions:
Prior authorization is not required for beneficiaries with a diagnosis of pain secondary to cancer.

Prior authorization is not required on <u>preferred short-acting opioids</u> up to the equivalent daily maximum dose of 90 MME/day for beneficiaries with Sickle Cell Disease.

Criteria:

<u>Short-Acting preferred Opioid Analgesics</u>

- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 1) or greater than the maximum daily dose per claim (Table 3).
- Prior approval is required for greater than 5 days supply for acute pain and 7 days supply for postoperative pain.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding dose per day limits and duration (days supply) limits.

- Prior approval requests may be approved for up to 6 months
- Reauthorization prior approval requests for beneficiaries with chronic pain must include documentation as to why the beneficiary needs continued opioid treatment and current plan of care
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Short-Acting Non-preferred Opioid Analgesics

- Prior approval required for all non-preferred short acting-opioids
- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 1) or greater than the maximum daily dose per claim (Table 3).
- Prior approval required for greater than 5 days supply for acute pain and 7 days supply for postoperative pain.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding dose per day limits and duration (days supply) limits.
- Reauthorization prior approval requests for beneficiaries with chronic pain must include documentation as to why the beneficiary needs continued opioid treatment and current plan of care
- Prior approval requests may be approved for up to 6 months.
- The Beneficiary must have a documented failure within the past year of ~~t~~two-preferred opioid analgesics at a dose equivalent to the dose of the product being prescribed or a known documented contraindication to one or more of the preferred ingredients (i.e. dye). The nature of treatment failure must be clearly documented in the chart
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain), and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.

- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).

- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Long-Acting Preferred Opioid analgesics

- The beneficiary shall have a diagnosis of moderate to severe pain with need for around-the-clock analgesia for an extended period.

- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 2) or greater than the maximum daily dose per claim (Table 3).

- Prior approval is required for beneficiaries who have not tried a short acting opioid in the past 45 days before trying long acting regardless of dose or days supply. Prior approval requests should include reason that beneficiary has not or cannot use a short acting first.

- Prior approval is required for greater than 7 days supply.

- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding limits

- Prior approval requests may be approved for up to 3 months.

- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain)
and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.

- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).

- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Long Acting Non-Preferred Opioid Analgesics

- The beneficiary shall have a diagnosis of moderate to severe pain with need for around-the-clock analgesia for an extended period.

- Prior approval is required for all non-preferred long acting opioids

- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 2) or greater than the maximum daily dose per claim (Table 3).
- Prior approval is required for greater than 7 days supply.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding limits
- Prior approval requests may be approved for up to 3 months.
- The Beneficiary must have a documented failure within the past year of two-preferred opioid analgesics at a dose equivalent to the dose of the product being prescribed or a known documented contraindication to one or more of the preferred ingredients (i.e. dye). The nature of treatment failure must be clearly documented in the chart
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Procedures

- Changes in strength will not require prior authorization.
- Prior authorization request forms will be accepted when submitted by facsimile telecommunication or web entry methods only.

Table 1

Short-acting- Daily dose limits for coverage	
Drug	**Dose equivalent to 90 MME/day**
benzhydrocodone	109.8mg/day
butorphanol	12.8mg/day
codeine products	600 mg/day
dihydrocodeine	900mg/day

Short-acting- Daily dose limits for coverage	
Drug	**Dose equivalent to 90 MME/day**
fentanyl citrate buccal, lozenges, sublingual (Abstral, Actiq, Fentora)	692 mcg/day
fentanyl citrate nasal spray (Lazanda)	562 mcg/day
fentanyl sublingual spray (Subsys)	500 mcg/day
hydrocodone/ acetaminophen	90 mg/day hydrocodone
hydrocodone	90 mg/day
hydromorphone (Dilaudid®)	24mg/day
morphine immediate-release	90mg/day
oxycodone immediate-release	60mg/day
oxycodone/ acetaminophen	60mg/day
oxycodone/aspirin	60mg/day oxycodone
oxycodone/ ibuprofen	60mg/day oxycodone
oxymorphone immediate- release (Opana®)	30mg/day

Short-acting- Daily dose limits for coverage	
Drug	**Dose equivalent to 90 MME/day**
pentazocine	272 mg/day
tramadol (Ultram® and Ultracet®)	400mg/day

NOTE: Dose in chart is equivalent to 90 mg morphine per day. MME values may exceed dosage recommendations. These values do not imply suggested dosing

Table 2

Long-acting daily dose limits for coverage	
Drug	**Dose equivalent to 90 MME/day**
Dolophine®, Methadose® (methadone)	22.5mg/day
Duragesic® (fentanyl transdermal)	37.5µg/hr (one patch every 72 hours)
Embeda® (morphine/naltrexone)	90/3.6 mg/day
Exalgo® (hydromorphone)	24 mg/day
Hysingla ER® (hydrocodone extended-release tablet)	90 mg/day
Kadian® (morphine extended-release)	90 mg/day

Long-acting daily dose limits for coverage	
Drug	**Dose equivalent to 90 MME/day**
levorphanol	8.1 mg/day
morphine extended-release capsule	90 mg/day
MS Contin®, Oramorph SR® (morphine controlled-release)	90mg/day
OxyContin® (oxycodone controlled-release)	60 mg/day
oxymorphone extended-release	30mg/day
tramadol ER (Conzip® and Ultram ER®)	300mg/day
Zohydro ER® (hydrocodone extended-release capsule)	90 mg/day

NOTE: Dose in chart is equivalent to 90 mg morphine per day. MME values may exceed dosage recommendations. These values do not imply suggested dosing

Table 3

Maximum daily dose per claim	
Drug	**Max Dose/Day**
acetaminophen products	4 grams/day Acetaminophen
ibuprofen products	3.2 grams/day ibuprofen

Maximum daily dose per claim	
Drug	**Max Dose/Day**
Aspirin products	4 grams/day aspirin
tramadol (Ultram® and Ultracet®)	400mg/day
tramadol ER (Conzip® and Ultram ER®)	300mg/day

References

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Criteria Change Log

03/04/2002	Criteria effective date- (original name Oxycontin)
08/04/2008	Name changed to Schedule II Narcotics
10/11/2012	Add Nucynta ER
03/13/2014	Add Zohydro
12/08/2014	Add Butrans NDC's
03/03/2015	Add new oxycodone GCN's
05/18/2015	Add Hysingla
06/10/2015	Add Embeda/Exalgo
06/16/2015	Add new morphine NDC's
01/21/2016	Add Lazanda, Oxecta
06/16/2016	Add Belbuca
08/27/2017	Dose limits changed to 120mme/day and limits added for 14 days supply
01/02/2018	limits added for 5 and 7 days supply
06/01/2018	Change daily limit to 90 mme and add CIII and CIV's
11/20/2018	Remove special criteria for Zohydro
02/13/2019	Add Roxybond
07/12/2019	Add Nalocet
09/17/2019	Add tramadol ER dose limits to chart. Were already programmed but only put in short acting chart originally. Add Apadaz and add benzhydrocodone MME's to chart Moved Conzip to Long Acting
07/09/2020	Updated EPSDT links Removed GCN's Added exemption for Sickle Cell for short acting opioids at 90mme's or less/day
03/01/2021	Removed obsolete products: Avinza, Endodan, Fioricet with codeine, Hycet, Magnacet, Onsolis, Oxecta, Percodan, Synalgos-DC & generic, Ultram ER, Vicoprofen, Xartemis XR, Xodol, Reprexain, and Zamicet Added: benzhydrocodone/APAP (generic Apadaz), Dsuvia, hydrocodone/ibuprofen (generic Ibudone), morphine sulfate ER (generic Avinza), buprenorphine patch (generic Butrans), tramadol ER capsule (generic Conzip), Morphabond ER Dose table clarification

WellCare of North Carolina
Prior Authorization
Criteria
Antiemetic Agents

Effective Date: 09/15/2010
Revised Date: 03/17/2021

Therapeutic Class Code: H6J
Therapeutic Class Description: Antiemetic Agents

Medication
Emend/ aprepitant

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

WellCare of North Carolina
Prior Authorization
Criteria
Antiemetic Agents

Effective Date: 09/15/2010
Revised Date: 03/17/2021

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

- Beneficiary is receiving:
  - Highly emetogenic chemotherapy OR
  - Carboplatin-based chemotherapy regimen OR
  - High-dose chemotherapy and stem cell or bone marrow transplantation
  - 4 or 5 day cisplatin-based chemotherapy regimen

AND

- Beneficiary is receiving concurrent use of dexamethasone (needed for regimen)

AND

- Beneficiary is receiving concurrent use of a 5HT3 receptor antagonist

AND

Dosage limits apply to each cycle:
- 125mg daily for one day
- Up to 80mg daily for 2 days.

Procedure:

Length of therapy may be approved for up to 12 months.

References

1. Antiemetic Agents, Topical. Drug Facts and Comparisons, Drug Facts and Comparisons, Wolters Kluwer Health. St. Louis (MO): updated monthly.

2. Prescriber Information-Emend ® (aprepitant), Merck and Co., Inc., Whitehouse Station, NJ., March 2010. Updated September 2019.

3. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. Journal of Clinical Oncology35, no. 28(October 01, 2017)3240-3261.

WellCare of North Carolina
Prior Authorization
Criteria
Antiemetic Agents

Effective Date: 09/15/2010
Revised Date: 03/17/2021

Criteria Change Log

09/15/2010	Criteria effective date
06/15/2012	Combined with NC Health Choice
06/12/2017	Added generic aprepitant to criteria and GCN 40344
03/17/2021	Removed post-op nausea and vomiting indication Removed requirement for trial and failure of 5HT3 Added requirement for concurrent use of 5HT3 Specified chemotherapy-induced nausea and vomiting indications as per ASCO guidelines

WellCare of North Carolina **Effective Date: March 4, 2002**
Prior Authorization Criteria **Amended Date: March 15, 2021**
Antinarcolepsy/Antihyperkinesis Agents

Therapeutic Class Code: H8Q, H1G
Therapeutic Class Description: Antinarcolepsy/Antihyperkinesis Agents

Medication
Provigil, modafinil
Nuvigil, armodafinil
Sunosi
Wakix
Xyrem
Xywaz

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age:
EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

A. Criteria for modafinil (Provigil) and armodafinil (Nuvigil)

Initial Approval Criteria

Approval will be considered as treatment to improve wakefulness for beneficiaries who:

- Have a diagnosis of narcolepsy. **OR**
- Have excessive sleepiness associated with shift work sleepdisorder. **OR**
- Require adjunct treatment for a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS) with concurrent use of continuous positive airway pressure (CPAP) if CPAP is the treatment of choice **OR**
- Have excessive fatigue associated with multiple sclerosis or myotonic dystrophy

Procedure

- Approval length one year.
- The maximum daily dose for modafinil is 400 mg.

- The maximum daily dose for armodafinil is 250 mg.

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**
- Beneficiary reports documented reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale)

B. Criteria for Sunosi

Initial Approval Criteria

Approval will be considered as treatment to improve wakefulness for beneficiaries who:

- Are ≥ 18 years old; **AND**
- Have a diagnosis of obstructive sleep apnea (OSA) OR narcolepsy; **AND**
- Do not have end stage renal disease (estimated glomerular filtration rate [eGFR] < 15 mL/min/1.73 m2); **AND**
- Have blood pressure assessed and hypertension controlled (≤ 140/90 mmHg) prior to initiating treatment; **AND**
- Are not receiving a monoamine oxidase inhibitor (MAOI) and have not received a MAO inhibitor within 14 days; **AND**
- Are not receiving concomitant noradrenergic medications; **AND**
- Have tried and failed an adequate trial of at least one preferred drug in the Anti-Narcolepsy class on the NC Medicaid Preferred Drug List (PDL)**; AND**
- If used for OSA, beneficiary must meet the following requirements:
- Prescriber attestation that beneficiary is compliant with and will continue using positive airway pressure (PAP); **AND**
- Prescriber has excluded any other identifiable causes for patient's sleepiness (e.g., non-compliance with PAP, improperly fitted PAP mask, insufficient sleep, poor sleep hygiene, depression, and/or other sleep disorders);

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**
- Beneficiary has not developed increased blood pressure or heart rate that was not controlled by a dose reduction of solriamfetol or medical intervention. **AND**
- Beneficiary reports documented reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale

Procedure

- Initial approval duration: 3 months
- Renewal approval duration: 6 months

C. Criteria for Wakix

Initial Approval Criteria

- Beneficiary is ≥ 18 years old; **AND**
- Beneficiary has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months; **AND**
- Beneficiary must not be receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates); **AND**
- Beneficiary will not use drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin) concomitantly; **AND**
- Beneficiary will not use histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine) concomitantly; **AND**
- Beneficiary does not have a history of prolonged QTc interval (e.g., QTc interval > 450 milliseconds); **AND**
- Beneficiary does NOT have end-stage renal disease (estimated glomerular filtration rate [eGFR] < 15 mL/min/1.73 m2); **AND**
- Beneficiary does NOT have severe hepatic impairment; **AND**
- Beneficiary has a diagnosis of cataplexy with narcolepsy; **OR**

- Beneficiary has a diagnosis of narcolepsy; **AND**
    - Beneficiary must have had an adequate documented trial and failure of, or contraindication to, modafinil and armodafinil

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**
- For diagnosis of narcolepsy: Beneficiary reports documented reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- For diagnosis of cataplexy with narcolepsy: reduced frequency of cataplexy attacks from pretreatment baseline
- Beneficiary has NOT experienced any treatment-restricting adverse effects(e.g., abnormal behavior, abnormal dreams or nightmares, anhedonia, anxiety, bipolar disorder, depression or depressed mood, nausea, QT prolongation, sleep disorder, suicide attempt or suicidal ideation).

D. Criteria for Xyrem & Xywaz

Initial Approval Criteria

- Beneficiary is ≥ 7 years of age; **AND**
- Beneficiary has no current use of alcohol, or sedative hypnotics; **AND**
- Beneficiary does not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Beneficiary has been evaluated for history of drug abuse; **AND**
- Prescriber will monitor for signs of misuse or abuse of sodium oxybate (a.k.a. gamma-hydroxybutyrate [GHB]) including, but not limited to, the following:
    - Use of increasingly large doses, increased frequency of use, drug seeking behavior, feigned cataplexy, etc.; **AND**
- Diagnosis of cataplexy associated with narcolepsy; **OR**
- Diagnosis of excessive daytime sleepiness due to narcolepsy with daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months; AND
    - Hypersomnolence secondary to another sleep disorder, neurologic disorder, medical condition, or by medicine or substance use has been ruled out

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**
- For Excessive Daytime Sleepiness: Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); AND
- For Cataplexy - reduced frequency of cataplexy attacks from pretreatment baseline

References

1. Prescriber Information—PROVIGIL® (pro-vij-el) Tablets [C-IV]—Generic name: modafinil. Cephalon, Inc. West Chester, PA 19380. February 2004.
2. Ballon JS, Feifel D. A systematic review of modafinil: potential clinical uses and mechanisms of action. *Journal of Clinical Psychiatry.* 2006 April; 67(4):554-566.
3. Fava M, Thase ME, DeBattista C. A multicenter, placebo controlled study of Modafinil augmentation in partial responders to selective serotonin reuptake inhibitors with persistent fatigue and sleepiness. *Journal of Clinical Psychiatry.* 2005 January; 66(1):85-93.
4. Prescriber Information—NUVIGIL ® (armodafinil) Tablets (C-IV). Cephalon, Inc. Frazer, PA 19355. July 2008.
5. Lange Rudiger,et al. Modafanil effects in multiple sclerosis patients with fatigue. *Journal of Neurology.* 2009 April; 256: 645-650.
6. Rammohan, K, et al. Efficacy and Safety of modafinil (Provigil®) for the treatment of fatigue in multiple sclerosis: a two centre phase 2 study. *Journal of Neurology, Neurosurgery, and Psychiatry.* 2002:72:179-183.
7. Prescriber Information- SUNOSI®. Palo Alto, CA; Jazz; March 2019.
8. Wakix [package insert]. Plymouth Meeting, PA; Harmony Biosciences; August 2019. Updated October 2020
9. Xywav [package insert]. Palo Alto, CA; Jazz; July 2020.
10. Xyrem [package insert]. Palo Alto, CA; Jazz; July 2020.

Criteria Change Log	
03/04/2002	Criteria effective date
07/10/2007	Added requirement for CPAP and diagnosis of Obstructive Sleep Apnea/Hypopnea Syndrome
08/10/2009	Added coverage for Nuvigil
09/14/2011	Added coverage for diagnoses of Multiple Sclerosis and Myotonic Dystrophy
06/15/2012	Added modafinil and Nuvigil
09/13/2012	Added GCN 36082 for Nuvigil
05/22/2018	Added armodafinil
10/13/2020	Removed GCN's Added Sunosi Updated EPSDT information Added criteria for Wakix
03/15/2021	Added criteria for Xyrem & Xywaz Added cataplexy with narcolepsy as approvable diagnosis for Wakix

WellCare of North Carolina
Prior Authorization Criteria
Cystic Fibrosis **Effective Date: November 14, 2012**
Amended Date: March 15, 2021

Therapeutic Class Code: B0B, B0F

Therapeutic Class Description: CFTR (Cystic Fibrosis Transmembrane Conductance Regulator) Potentiator, and CFTR Potentiator and Corrector Combination

Medication
Kalydeco 150mg tablets Kalydeco 50mg granules Kalydeco 75mg granules Kalydeco 25mg granules
Orkambi 200mg/125mg tablets Orkambi 100mg/125mg tablets Orkambi 150/188mg granules Orkambi 100/125mg granules
Symdeko 50mg/75mg -75 mg tablets Symdeko 100/150 mg - 150 mg tablets
Trikafta

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical

practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Coverage- Kalydeco:

- Beneficiary has been diagnosed with Cystic Fibrosis
  and
- Beneficiary is age 4 months or greater
  and
- Beneficiary has a documented mutation in the CFTR gene that is responsive to ivacaftor. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. (KALYDECO is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene)
  and
- Dosing is 150mg taken every 12 hours (300mg/day total) or less
  and
- A baseline ALT and AST assessed prior to beginning therapy

Criteria for Coverage- Orkambi:

- Beneficiary has been diagnosed with Cystic Fibrosis

and

- Beneficiary is age 2 or greater

and

- Beneficiary is documented as homozygous for the *F508del* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene.

and

- Dosing is two tablets (each containing lumacaftor 200 mg/ivacaftor 125 mg) or less taken orally every 12 hours with fat-containing food

and

- A baseline ALT and AST assessed prior to beginning therapy

Criteria for Coverage- Symdeko:

- Beneficiary has been diagnosed with Cystic Fibrosis

and

- Beneficiary is 6 years of age or greater

and

- Beneficiary is documented as homozygous for the F508del mutation in the CFTR gene or beneficiary has one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

and

- Dosing is one tablet in the morning and one tablet in the evening

and

- A baseline ALT and AST assessed prior to beginning therapy

Criteria for Coverage- Trikafta:

- Beneficiary has been diagnosed with Cystic Fibrosis

and

- Beneficiary is 12 year of age or greater

and

- Beneficiary is documented to have at least one copy of the F508del mutation in the CFTR gene. If the beneficiary's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation.

and

- Dosing does not exceed: two tablets (elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening

and

- Baseline ALT, AST, and bilirubin have been assessed prior to beginning therapy

and

- If beneficiary less than 18 year of age: baseline ophthalmic examination has been performed

Procedures:

Length of therapy may be approved for up to 12 months.

References

1. Prescribing Information-Kalydeco® (ivacaftor) Vertex Pharmaceuticals, Inc., Cambridge, Massachusetts 02139. January 2012.

2. Prescribing Information Kalydeco®. Vertex Pharmaceuticals Incorporated Cambridge, MA; February 2014.

3. Prescribing Information Orkambi®. Vertex Pharmaceuticals Incorporated Boston, MA; April 2015.

4. Prescribing Information Orkambi®. Vertex Pharmaceuticals Incorporated Boston, MA; September 2016. Revised July 2019.

5. Prescribing Information Kalydeco®. Vertex Pharmaceuticals Incorporated Cambridge, MA; March 2015.

6. Prescribing Information Kalydeco®. Vertex Pharmaceuticals Incorporated Cambridge, MA; May 2017. Revised April 2019. Revised September 2020.

7. Prescribing Information Symdeko. Vertex Pharmaceuticals, Inc. Cambridge, MA; February 2018. Revised June 2019.

WellCare of North Carolina
Prior Authorization Criteria
Cystic Fibrosis **Effective Date: November 14, 2012**
Amended Date: March 15, 2021

Criteria Change Log

11/14/2012	Criteria effective date-Kalydeco only
08/01/2014	Added G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. (KALYDECO is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene)
04/01/2015	Added R117H mutation
11/05/2015	Added Kalydeco gcn's 38138, 38139
03/09/2016	Added coverage for Orkambi
04/06/2017	Changed age for Kalydeco to 2 yrs and older and for Orkambi to 6 yrs and older
10/03/2017	Added genetic mutations E56K, K1060T, P67L, E193K, A1067T, R74W, L206W, G1069R, D110E, R347H, D579G, R1070Q, D1270N, D110H, R352Q, S945L, R1070W, R117C, A455E, S977F, F1074L, F1052V,or D1152H for Kalydeco
06/11/2018	Added information about Symdeko
02/26/2019	Age for Kalydeco changed from 2 or greater to 1 or greater
	Age for Symdeko changed from 12 or greater to 6 or greater. Updated GCN's with new products
11/03/2020	Removed GCN's Age for Kalydeco changed from 1 or greater to 6 months or greater. Age for Orkambi changed from 6 or greater to 2 or greater. Removed GCNs. Removed G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, R117H, E56K, K1060T, P67L, E193K, A1067T, R74W, L206W, G1069R, D110E, R347H, D579G, R1070Q, D1270N, D110H, R352Q, S945L, R1070W, R117C, A455E, S977F, F1074L, F1052V, or D1152H and replaced with mutation in the CFTR gene that is responsive to ivacaftor. Updated EPSDT web addresses and info
11/03/2020	Added Trikafta
03/15/2021	Age for Kalydeco changed from 6 months or greater to 4 months or greater.

WellCare of North Carolina **Effective Date: February 26, 2019**
Prior Authorization Criteria **Amended Date: March 11, 2021**
Migraine Therapy
Calcitonin Gene-Related Inhibitors

Therapeutic Class Code: H3F
Therapeutic Class Description: Migraine Therapy- Calcitonin Gene-Related Peptide Inhibitors

Medication
Preventative treatment of migraines in adults:
Aimovig 70mg/ml autoinjector
Aimovig 140mg/ml autoinjector
Ajovy 225mg/1.5ml autoinjector
Ajovy 225mg/1.5ml syringe
Emgality 120mg/ml pen
Emgality 120mg/ml syringe
Emgality 120mg/ml pen
Vyepti 100 mg/ml vial
Treatment of episodic cluster headache in adults
Emgality 100mg/ml syringe (set of 3)
Acute Treatment of Migraines, with or without aura
Nurtec ODT 75 mg tablets
Ubrelvy 50 mg tablets
Ubrelvy 100 mg tablets

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.

b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or

ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
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EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

A. Preventative Treatment of Migraines (Aimovig, Ajovy, ~~and~~ Emgality 120mg/ml, and Vyepti)

Initial Criteria for Coverage

1. Beneficiary has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders criteria;

2. Beneficiary is 18 years old or older;

3. Beneficiary does not have medication over-use headache (MOH);

4. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline;

5. Beneficiary has 4 or more migraine days per month for at least 3 months;

6. Beneficiary is utilizing prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) ;

7. Beneficiary has tried and failed at least a month or greater trial of medications from at least 2 different classes from the following list of oral medications:

   a. Antidepressants (e.g. amitriptyline, venlafaxine)

   b. Beta Blockers (e.g. propranolol, metoprolol, timolol, atenolol)

   c. Anti-epileptics (e.g. valproate, topiramate)

   d. Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan)

   e. Calcium Channel Blockers (e.g. verapamil**,** nimodipine)

8. Initial approvals for up to a 3-month duration for Aimovig, Emgality, Ajovy monthly dosing; and

9. Initial approvals for up to a 6-month duration for Ajovy quarterly dosing and Vyepti.

Continuation of Coverage (renewal request) (Aimovig, Ajovy, and Emgality 120mg/ml)

1. Beneficiary has demonstrated significant decrease in the number, frequency, and/or intensity of headaches;

2. Beneficiary had experienced an overall improvement in function with therapy;

3. Beneficiary continues to utilize prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications);

4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status;

5. Beneficiary is not experiencing unacceptable toxicity (e.g. intolerable injection site pain, constipation); AND
6. Length of therapy may be approved for up to 12 months.

B. Treatment of Episodic Cluster Headache in Adults (Emgality 100mg/ml (set of 3)

Initial Criteria for Coverage

1. Beneficiary has a diagnosis of Episodic Cluster Headache with at least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of at least 3 months;

2. Beneficiary is 18 years old or older;

3. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline;

4. Beneficiary is utilizing prophylactic intervention modalities (e.g. medication therapy);

5. Beneficiary is receiving no more than 300mg (administered as three consecutive injections of 100mg each) at the onset of the cluster headache period, and then monthly until the end of the cluster headache period; and

6. Initial approvals for up to a 3-month duration.

Continuation of Coverage (renewal request) (Emgality 100mg/ml (set of 3)

1. Beneficiary has demonstrated decreases in the length, number, frequency, and/or intensity of headaches and/or a decrease in the length of the cluster period;

2. Beneficiary had experienced an overall improvement in function with therapy;

3. Beneficiary continues to utilize prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications, medications);

4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status;

5. Beneficiary is not experiencing unacceptable toxicity (e.g. intolerable injection site pain, constipation); AND
6. Length of therapy may be approved for up to 12 months

C. Acute Treatment of Migraines (Nurtec ODT 75mg and Ubrelvy 50 mg & 100 mg tablets)

Initial Criteria for Coverage

1. Beneficiary must be ≥ 18 years of age;

2. Beneficiary must have a diagnosis of migraine, with or without aura;

3. Beneficiary must NOT have headache frequency ≥ 15 headache days per month during the prior 6 months;

4. Beneficiary must NOT be concurrently using a strong CYP3A4 inhibitor;

5. Beneficiary must NOT have end-stage renal disease (creatinine clearance [CrCl] < 15 mL/min);

6. Beneficiary must have tried and failed ≥ 1 of the following: NSAID, nonopioid analgesic, acetaminophen, OR caffeinated analgesic combination; AND

7. Beneficiary must have tried and failed, or have contraindication to, ≥ 2 preferred triptans.

Renewal Criteria

1. Beneficiary must continue to meet the above criteria;

2. Beneficiary must demonstrate resolution in headache pain or reduction in headache severity, as assessed by prescriber; AND

3. Beneficiary has not have experienced any treatment-restricting adverse effects (e.g., nausea, somnolence, dry mouth).

References

1. Aimovig package insert, Amgen, Inc., Thousand Oaks, CA., May 2018.

2. Ajovy package insert, Teva Pharmaceuticals, USA, Inc., North Wales, PA. updated September 2018.

3. Emgality package insert, Eli Lilly and Co., Indianapolis, IN., updated September 2018. updated June 2019

4. Ubrelvy [package insert]. Madison, NJ; Allergan; December 2019.

5. Nurtec ODT [package insert]. New Haven, CT; Biohaven. February 2020.

6. Vyepti [package insert]. Bothell, WA; Lundbeck Seattle; February 2020.

Criteria Change Log

02/26/2019	Criteria effective date
12/04/2019	Added coverage for Episodic Cluster Headache in Adults
03/11/2021	Added Ubrelvy
03/11/2021	Added Nurtec ODT and Vyepti

WellCare of North Carolina
Prior Authorization Criteria **Effective Date: November 1, 2011**
Monoclonal Antibody **Amended Date: March 15, 2021**

Therapeutic Class Code: Z2L, Z2O, V4D
Therapeutic Class Description: Monoclonal Antibody

Medication
Xolair
Fasenra
Nucala
Dupixent

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

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1. Xolair

A. Allergic Asthma:

Criteria for Initial Therapy of Xolair (Allergic Asthma):

The beneficiary must meet **all** of the following criteria:

1) be 6 years of age and older weighing between 20 kg (44 lbs) and 150kg (330 lbs);
2) have a diagnosis of asthma;
3) have inadequately controlled asthma meeting one of the following definitions:
   a. Use of inhaled corticosteroids in the past 45 days and excessive use of short-acting beta agonists in the past 60 days; **OR**

b. Use of inhaled corticosteroids in the past 45 days and short-term oral steroid use in the past 45 days; **OR**
c. Use of inhaled corticosteroids in the past 45 days and an emergency room visit in the past 45 days;

4) A percutaneous skin test or RAST allergy test in the past twelve months indicating reactivity to at least one perennial aeroallergen;
5) IgE level above 30 IU/mL.

Approval length up to 12 months.

Criteria for Continuation of Therapy of Xolair (Allergic Asthma):
For beneficiaries already receiving Xolair, coverage is provided when there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical records documenting the beneficiary's current asthma status, response to Xolair treatment, and current smoking status.

Approval length up to 12 months.

B: <u>Chronic Idiopathic Urticaria for Xolair:</u>

Criteria for Initial Therapy of Xolair (Chronic Idiopathic Urticaria):

1) Covered for beneficiaries 12 years of age and above with moderate to severe chronic idiopathic urticaria who remain symptomatic despite treatment with at least two H1 antihistamines and one leukotriene modifier.

2) Omalizumab should also be prescribed in consultation with an allergy specialist.

Criteria for Continuation of Therapy of Xolair (Chronic Idiopathic Urticaria):

For beneficiaries already receiving Xolair, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit from baseline supported by medical records.

2. Fasenra

A. <u>Severe Asthma:</u>

Criteria for Initial Therapy of Fasenra (Asthma):

The beneficiary must meet **all** of the following criteria:

1) be 12 years of age and older;
2) have a diagnosis of severe eosinophilic asthma;

3) have a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past 6 weeks prior to the request for Fasenra) or 300 cells/mcL or greater within 12 months prior to use, or sputum eosinophilic count greater than 3%;
4) have inadequate control of asthmatic symptoms after a minimum of 3 months of high dose corticosteroid inhaler in combination with a long acting beta-agonist;
5) have inadequately controlled severe asthma meeting one of the following definitions:

a. 2 or more asthma exacerbations requiring oral/systemic corticosteroid treatment; or
b. hospitalization in the past 12 months;

6) have prebronchodilator FEV1 below 80% in adults and 90% in adolescents;
7) Fasenra is being used as add on maintenance treatment;
8) Fasenra is not being used for the treatment of other eosinophilic conditions;
9) Fasenra is not being used for the relief of acute bronchospasm or status asthmaticus;
10) Fasenra is not being used as dual therapy with other monoclonal antibody treatments; **and**

Initial approval up to 6 months.

Criteria for Continuation of Therapy of Fasenra (Asthma):
For beneficiaries already receiving Fasenra, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical records documenting the beneficiary's current asthma status and response to Fasenra treatment

Approval length up to 12 months.

3. Nucala

A. <u>Asthma</u>

Criteria for Initial Therapy (Asthma):

The beneficiary must meet **all** of the following criteria:

1) be 6 years of age or older
2) have a diagnosis of severe eosinophilic asthma;
3) have a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past six weeks prior to the request for Fasenra) or 300 cells/mcL or greater within 12 months prior to use, or sputum eosinophilic count greater than 3%;
4) have inadequate control of asthmatic symptoms after a minimum of 3 months of high dose corticosteroid inhaler in combination with a long acting beta-agonist
5) have inadequately controlled severe asthma meeting one of the following definitions:
a. two or more asthma exacerbations requiring oral/systemic corticosteroid treatment; or
b. hospitalization in the past 12 months;
6) have prebronchodilator FEV1 below 80% in adults and 90% in adolescents;
7) Nucala is being used as add on maintenance treatment;

8) Nucala is not being used for the treatment of other eosinophilic conditions
9) Nucala is not being used for the relief of acute bronchospasm or status asthmaticus
10) Nucala is not being used as dual therapy with other monoclonal antibody treatments; **and**

Initial approval up to 6 months.

Criteria for Continued Therapy (Asthma):
For beneficiaries already receiving Nucala, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical records documenting the beneficiary's current asthma status and response to Nucala treatment.

Approval length up to 12 months.

B. Eosinophilic Granulomatosis with Polyangiitis

Criteria for Initial Therapy (Polyangiitis):
The beneficiary must have the following:

1) Confirmed diagnosis of Eosinophilic Granulomatosis with Polyangiitis
2) Be 18 years old or older

Approval length up to 6 months.

Criteria for Continued Therapy (Polyangiitis):
For beneficiaries already receiving Nucala, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit from baseline supported by medical records.

Approval length up to 12 months.

4. Dupixent

A. Atopic Dermatitis

Criteria for Initial Therapy (Atopic Dermatitis)

The beneficiary must meet **all** of the following criteria:

1. be 6 years of age or older
2. have a diagnosis of moderate to severe Atopic Dermatitis
3. have failed at least 2 prescription topical steroids or have a documented adverse reaction or contraindication that precludes trial of at least 2 prescription topical steroids
4. have tried and failed on either Protopic, Elidel, Eucrisa, or tacrolimus or has a

documented adverse reaction or contraindication that precludes trial of either Protopic, Elidel, Eucrisa or tacrolimus.

Approval length up to six months

Criteria for Continuation of Therapy of Dupixent (Atopic Dermatitis):

For beneficiaries already receiving Dupixent, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit from baseline supported by medical records.

B. Asthma

Criteria for Initial Therapy (Asthma)

1. Beneficiary is 12 years of age or older and has **ONE** of the following:
   a. A diagnosis of Asthma with eosinophilic phenotype with a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past six weeks prior to the request for Dupixent) or 300 cells/mcL or greater within 12 months prior to use, or sputum eosinophilic count greater than 3% **OR**
   b. Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months **AND**
2. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use of **ONE** of the following within the past 6 months:
   a. Inhaled corticosteroids & long acting beta2 agonist **OR**
   b. Inhaled corticosteroids & long acting muscarinic antagonist **AND**
3. **NOT** being used for the relief of acute bronchospasm or status asthmaticus **AND**
4. **NOT** receiving dual therapy with another monoclonal antibody for the treatment of asthma

Approval length up to six months

Criteria for Continued Therapy (Asthma):
For beneficiaries already receiving Dupixent, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical records documenting the beneficiary's current asthma status and response to Dupixent treatment.

C. Nasal Polyps

Criteria for Initial Therapy (Nasal Polyps)

1. Beneficiary is 18years of age or older; **AND**
2. Has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND**
3. Has failed monotherapy with nasal steroids; **AND**
   a. Has had previous sino-nasal surgery, OR

b. Has had treatment for nasal polyps with systemic corticosteroids in the past 2 years, or has contraindication to systemic corticosteroids; AND

4. Must continue to receive intranasal steroid concomitantly

References

1. Genentech, Inc. Xolair Package Insert. San Francisco, CA. September 2014.

2. Astra Zeneca, Inc. Fasenra Package Insert. Wilmington, DE. November 2017.

3. GlaxoSmithKline, LLC. Nucala Package Insert. Philadelphia, PA. November 2015, updated September 2019.

4. Regeeneron Pharmaceuticals, INC. Dupixent package insert. Tarrytown, NJ: March 2017, updated May 2020.

Criteria Change Log

11/01/2011	Criteria effective date (Xolair only)
05/20/2015	Criteria amended to include Chronic Idiopathic Urticaria for Xolair
04/26/2016	Nucala criteria effective
04/05/2018	Added criteria for Fasenra
05/04/2018	Added coverage for Eosinophilic Granulomatosis with Polyangiitis for Nucala
06/01/2018	Combined Nucala with Xolair and Fasenra into 1 criteria
11/20/2018	Add continuation criteria for Xolair for Idiopathic Urticaria and Nucala for Granulomatosis Polyangiitis, change eosinophilic count to 150 cells/mcl for Fasenra and Nucala.
06/10/2019	Added Dupixent to monoclonal antibody criteria and added additional criteria for Dupixent for Asthma diagnosis. Added 2 new GCN's for Xolair.
01/29/2020	Removed GSNs. Added nasal polyp criteria to Dupixent. Added weight to Xolair for Allergic Asthma.
03/15/2021	Change age requirement for Nucala for asthma from 12 years to 6 years.
03/15/2021	Change age for Dupixent used for Atopic Dermatitis from 12 years to 6 years.

WellCare of North Carolina
Prior Authorization Criteria **Effective Date: August 15, 2014**
Systemic Immunomodulators **Amended Date: March 15, 2021**

Therapeutic Class Code: D6K, S2J, S2M, S2Q, Z2U, Z2Z, S2Z, L1A, S2V, Z2V, D6K, Z27
Therapeutic Class Description: Immunomodulatory Agents

Medication	Medication	Medication
Actemra SQ	Ilumya	Siliq
Actemra Infusion	Inflectra Infusion	Simponi
Arcalyst	Kevzara	Simponi Aria Infusion
Avsola Infusion	Kineret	Skyrizi
Cimzia	Olumiant	Stelara
Cosentyx	Orencia Infusion	Stelara Infusion
Enbrel	Orencia SQ	Taltz
Enspryng	Otezla	Tremfya
Entyvio Infusion	Remicade Infusion	Uplizna
Humira	Renflexis	Xeljanz and Xeljanz XR
Ilaris	Rinvoq ER	

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correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

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Criteria

1. **Ankylosing Spondylitis**: For Enbrel, Humira, Cosentyx, Avsola Cimzia, Inflectra, Simponi, Simponi Aria, Remicade, Taltz and Renflexis ONLY.

- Beneficiary has a diagnosis of Ankylosing Spondylitis
  AND
- Beneficiary is not on another injectable biologic immunomodulator
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Beneficiary has experienced inadequate symptom relief from treatment with at least two NSAIDS
  OR
- Beneficiary is unable to receive treatment with NSAIDS due to contraindications.
  OR
- Beneficiary has clinical evidence of severe or rapidly progressing disease
  AND

- Coverage of non-preferred medications require a trial and failure of Cosentyx, Enbrel or Humira or a clinical reason beneficiary cannot try Cosentyx, Enbrel or Humira.

2. Crohn's disease (Adult): For Humira, Avsola, Cimzia, Entyvio, Inflectra, Stelara, Stelara Infusion Remicade and Renflexis ONLY.

- Beneficiary has a diagnosis of moderate to severe Crohn's Disease.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira

3. Crohn's disease (Pediatric): For Humira, Avsola, Inflectra, Remicade, and Renflexis ONLY

- Beneficiary has a diagnosis of moderate to severe Crohn's Disease.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira

4. Polyarticular Juvenile Idiopathic Arthritis (PJIA): For Enbrel, Humira, Actemra SQ, Actemra Infusion, Simponi Aria, Orencia Infusion, Orencia SQ, and Xeljanz ONLY.

- Beneficiary has a diagnosis of Polyarticular Juvenile Idiopathic Arthritis
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Beneficiary has tried one systemic corticosteroid (e.g. prednisone, methylprednisolone) or methotrexate, leflunomide or sulfasalazine with inadequate response or is unable to take these therapies due to contraindications.
  OR
- Beneficiary has PJIA subtype enthesitis related arthritis
  AND
- Coverage of non-preferred medications require a trial and failure of Enbrel or Humira or a clinical reason beneficiary cannot try Enbrel or Humira.

5. Systemic Onset Juvenile Idiopathic Arthritis.(SJIA): For Actemra Infusion, Actemra SQ and

Ilaris ONLY.

- Beneficiary has a diagnosis of Systemic Juvenile Idiopathic arthritis
- AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has a diagnosis of Systemic Juvenile Idiopathic arthritis
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  OR
- Beneficiary has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g. arthritis of the hip, radiographic damage)

6. Neonatal Onset Multisystem Inflammatory Disease (NOMID): For Kineret ONLY.

- Beneficiary has a diagnosis of neonatal-onset multisystem inflammatory disease
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

7. Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): For Arcalyst and Ilaris ONLY.

- Beneficiary has a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

8. Plaque psoriasis (Pediatric): For Enbrel, Stelara (ages 6 and up), and Taltz (ages 6 and up) ONLY.

- Beneficiary has a diagnosis of plaque psoriasis and is a candidate for systemic therapy or phototherapy
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Beneficiary has experienced a therapeutic failure/inadequate response with or has a

contraindication or intolerance to methotrexate.
AND

- Beneficiary has body surface area (BSA) involvement of at least 3%.
OR
- Beneficiary has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment.
AND
- For ages 6 and up, coverage of non-preferred medications requires a trial and failure of Enbrel or a clinical reason beneficiary cannot try Enbrel.

9. Plaque psoriasis (adult): For Enbrel, Humira, Cosentyx, Avsola, Cimzia, Ilumya, Inflectra, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Stelara, Taltz, and Tremfya ONLY.

- Beneficiary has a documented definitive diagnosis of moderate-to-severe chronic plaque psoriasis
AND
- Beneficiary is 18 years of age or older
AND
- Beneficiary is not on another injectable biologic immunomodulator.
AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection (not required for Otezla).
AND
- Beneficiary has been tested with Hep B SAG and Core Ab (not required for Otezla).
AND
- Beneficiary has body surface area (BSA) involvement of at least 3%.
OR
- Beneficiary has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment.
AND
- Beneficiary has failed to respond to, or has been unable to tolerate phototherapy and **ONE** of the following medications or beneficiary has contraindications to these treatments:
  - Soriatane (acitretin)
  - Methotrexate
  - Cyclosporine

AND
- Coverage of non-preferred medications require a trial and failure of Cosentyx, Enbrel or Humira or a clinical reason beneficiary cannot try either Cosentyx, Enbrel or Humira.
AND
- Beneficiaries, Providers, and Pharmacies utilizing Siliq must be registered appropriately in the Siliq Risk Evaluation and Mitigation Strategy Program (REMS program).

10. Psoriatic arthritis: For Enbrel, Humira, Cosentyx, Avsola, Cimzia, Inflectra,Orencia SQ, Orencia Infusion, Otezla, Renflexis, Remicade, Simponi, Simponi Aria, Stelara, Taltz, Tremfya, Xeljanz and Xeljanz XR ONLY

- Beneficiary has a documented definitive diagnosis of psoriatic arthritis
AND
  - Beneficiary is 18 years of age or older (OR 2 years or older for Simponi Aria)
AND
  - Beneficiary is not on another injectable biologic immunomodulator.

AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection (not required for Otezla).
- AND
- Beneficiary has been tested with Hep B SAG and Core Ab (not required for Otezla).
  AND
- Beneficiary has a documented inadequate response or inability to take methotrexate
  AND
- Coverage of non-preferred medications require a trial and failure of Cosentyx, Enbrel or Humira or a clinical reason beneficiary cannot try either Cosentyx, Enbrel or Humira.

11. Rheumatoid arthritis: For Enbrel, Humira, Actrema Infusion, Actemra SQ, Avsola,Cimzia, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Orencia SQ, Remicade, Renflexis, Rinvoq ER, Simponi, Simponi Aria, Xeljanz and Xeljanz XR ONLY
- Beneficiary has a diagnosis of Rheumatoid Arthritis
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Beneficiary has experienced a therapeutic failure/inadequate response with methotrexate or at least one disease modifying antirheumatic drug (e.g. leflunomide, hydroxychloroquine, minocycline, sulfasalazine).
  OR
- Beneficiary is unable to receive methotrexate or disease modifying antirheumatic drug due to contraindications or intolerabilities.
  OR
- Beneficiary has clinical evidence of severe or rapidly progressing disease
  AND
- Coverage of non-preferred medications require a trial and failure of Enbrel or Humira or a clinical reason beneficiary cannot try either Enbrel or Humira.

12. Ulcerative colitis (Adult): For Humira, Avsola, Entyvio, Inflectra, Remicade, Renflexis, Stelara, Simponi, Xeljanz and Xeljanz XR ONLY.
- Beneficiary has a diagnosis of ulcerative colitis.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira

13. Ulcerative colitis (Pediatric): For Avsola, Remicade ONLY

- Beneficiary has a diagnosis of ulcerative colitis.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

14. Hidradenitis Suppurativa: For Humira ONLY (ages 12 and older)

- Beneficiary has a diagnosis of Hidradenitis Suppurativa (moderate to severe).
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

15. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS); Ilaris ONLY

- Beneficiary has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

16. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD): Ilaris ONLY

- Beneficiary has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

17. Familial Mediterranean Fever (FMF): Ilaris ONLY

- Beneficiary has a diagnosis of Familial Mediterranean Fever (FMF)
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

18. Non-infectious Intermediate Posterior Panuveitis: Humira ONLY (ages 2 and older)

- Beneficiary has a diagnosis of Non-infectious Intermediate Posterior Panuveitis

AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

19. Giant Cell Arteritis: Actemra and Actemra SQ ONLY
- Beneficiary has a diagnosis of Giant Cell Arteritis
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

20. Cytokine Release Syndrome: Actemra and Actemra SQ ONLY
- Beneficiary has a diagnosis of Cytokine Release Syndrome
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

21. Non-Radiographic Axial Spondyloarthritis: Cimzia, Cosentyx, and Taltz ONLY
- Beneficiary has a diagnosis of Non-Radiographic Axial Spondyloarthritis
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has failed an adequate trial of a Non-Steroidal Anti-Imflammatory Drug (NSAID) unless contraindicated.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  AND
- Coverage of non-preferred medications require a trial and failure of Cosentyx

22. Oral Ulcers associated with Behcet's Disease: Otezla ONLY

- Beneficiary has a documented diagnosis of Behcet's disease
  AND
- Beneficiary is 18 years of age or older
  AND
- Beneficiary is not on another injectable biologic immunomodulator.

23. Adult Onset Still's Disease: Ilaris ONLY
- Beneficiary has a diagnosis of Adult Onset Still's Disease

AND

- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  OR
- Beneficiary has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g. arthritis of the hip, radiographic damage)

24. Neuromyelitis Optica Spectrum Disorder (NMOSD): Uplizna and Enspryng

- Beneficiary has a diagnosis of Neuromyelitis Optica Spectrum Disorder
  AND
- Beneficiary is anti-aquaporin-4 (AQP4) antibody positive
  AND
- Beneficiary is 18 years of age or older
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab

Procedures

- Approve for up to 12 months.
- Coverage of one injectable immunomodulator at a time.

WellCare of North Carolina
Prior Authorization Criteria
Systemic Immunomodulators

Effective Date: August 15, 2014
Amended Date: March 15, 2021

	Enbrel (P)	**Humira (P)**	**Cosentyx (P)**	Actemra Infusion/ Actemra SQ	Arcalyst	Avsola	Cimzia	Enspryng	Entyvio	Ilaris	Ilumya	Inflectra	Kevzara	Kineret	Olumiant	Orencia/ Orencia SQ	Otezla	Remicade	Renflexis	Rinvoq ER	Siliq	Simponi	Simponi Aria	Skyrizi	Stelara	Stelara Infusion	Taltz	Tremfya	Uplinzna	Xeljanz/ Xeljanz XR
Anklyosing Spondylitis	X	X	X			X***	X***					X***						X***	X***			X***	X***				X***			
Crohn's Disease (adult)		X				X*	X*		X*			X*						X*	X*						X*	X*				
Crohn's Disease (pediatric)		X				X*						X*						X*	X*											
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	X	X		X**												X**							X**							X**
Systemic Onset Juvenile Idiopathic Arthritis (SJIA)				X						X																				
Neonatal Onset Multisystem Inflammatory Disease (NOMID)														X													X			
Non-Radiographic Axial Spondyloarthritis			X				X*																				X*			
Cryoprin Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)					X					X																				
Plaque Psoriasis (pediatric)	X																								X* (ages 6 and up)		X* (ages 6 and up)			
Plaque Psoriasis (adult)	X	X	X			X***	X***				X***	X***					X***	X***	X***		X***			X***	X***		X***	X***			
Psoriatic Arthritis	X	X	X			X***	X***					X***				X***	X***	X***	X***			X***	X***		X***		X***	X***			X***
Rheumatoid Arthritis	X	X		X**		X**	X**					X**	X**	X**	X**	X**		X**	X**	X**		X**	X**								X**
Ulcerative Colitis (adult)		X				X*			X*			X*						X*	X*			X*									X*
Ulcerative Colitis (pediatric)						X*												X													
Hidradenitis Suppurativa		X																													
Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)										X																					

WellCare of North Carolina
Prior Authorization Criteria
Systemic Immunomodulators

Effective Date: August 15, 2014
Amended Date: March 15, 2021

	Enbrel (P)	**Humira (P)**	**Cosentyx (P)**	Actemra Infusion/ Actemra SQ	Arcalyst	Avsola	Cimzia	Enspryng	Entyvio	Ilaris	Ilumya	Inflectra	Kevzara	Kineret	Olumiant	Orencia/ Orencia SQ	Otezla	Remicade	Renflexis	Rinvoq ER	Siliq	Simponi	Simponi Aria	Skyrizi	Stelara	Stelara Infusion	Taltz	Tremfya	Uplinzna	Xeljanz/ Xeljanz XR
Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)										X																				
Familial Mediterranean Fever (FMF)										X																				
Non-Infectious Intermediate Posterior Panuveitis		**X**																												
Giant Cell Arteritis				X																										
Cytokine Release Syndrome				X																										
Behcet's Disease																	X													
Adult Onset Still's Disease										X																				
Neuromyelitis Optica Spectrum Disorder (NMOSD)								X																					X	

*Trial and failure of Humira before coverage of non-preferred agent

** Trial and failure of Enbrel or Humira before coverage of non-preferred agent

*Trial and Failure of Enbrel before coverage of non-preferred

***Trial and failure of either Cosentyx, Enbrel or Humira before coverage of non-preferred agent

*Trial and Failure of Cosentyx before coverage of non-preferred

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Criteria Change Log

08/15/2014	Criteria effective date
06/10/2015	add Otezla and add gcn 37262 for Humira
01/21/2016	add Cosentyx
06/13/2016	add dx Hidradenitis Suppurativa for Humira
10/03/2016	add Xeljanz XR
10/19/2016	add Taltz
06/27/2018	add diagnosis for Ilaris- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), and Familial Mediterranean Fever (FMF) add diagnosis for Humira-Uveitis add Arcalyst to criteria coverage add infusion products to clinical coverage criteria- Actemra Infusion, Entyvio Infusion, Orencia Infusion, Remicade Infusion, Simponi Aria Infusion add new dx for Orencia- PHIA, Psoriatic Arthritis add Kevzara to criteria add diagnosis chart add Renflexis add Psoriatic Arthritis DX for coverage-Taltz add Psoriatic Arthritis DX for Xeljanz and Xeljanz XR
02/26/2019	update chart add Simponi Aria for DX Ankylosing Spondylitis, add Enbrel PJIA add Stelara Plaque Psoriasis (12 and up) add Cimzia Plaque Psoriasis adult add Otezla Psoriatic Arthritis remove Renflexis exception add Xeljanz/Xeljanx XR and Renflexis UC adults add Actemra and Actemra SQ to Giant Cell Arteritis and Cytokine Release Syndrome add Tremfya add Olumiant
07/18/2019	add ages for Humira in HS (12 and older) and Uveitis (2 and older) Include Cosentyx as try and fail for Anklyosing Spondylitis, Plaque Psoriasis, and Psoriatic Arthritis add Ilumya for Plaque Psoriasis (adult) update chart add Siliq
11/04/2019	Add Dx Non-Radiographic Axial Spondyloarthritis for Cimzia

12/09/2019	Removed GCN's, add Skyrizi to adult plaque psoriasis, add Stelara Infusion
03/15/2021	Added Taltz to Ankylosing Spondylitis, add Rinvoq ER Added Behcet's Disease for Otezla Updated EPSDT Information Updated table
03/15/2021	Add Stelara for ulcerative colitis for Adults Add Xeljanz XR for ulcerative colitis for adults Add contraindication or intolerance to methotrexate step for plaque psoriasis
03/15/2021	Add Taltz to plaque psoriasis for pediatrics & Non-Radiographic Axial Spondyloarthritis Add Avsola
03/15/2021	Added Cosentyx to Non-Radiographic Axial Spondyloarthritis Added bullet to Non-Radiographic Axial Spondyloarthritis requiring t/f of Cosentyx prior to approval of NP agent Added adult-onset Still's disease (AOSD) criteria for Ilaris Added Tremfya to psoriatic arthritis Added Enspryng & Uplinza for Neuromyelitis Optica Spectrum Disorder (NMOSD) to policy Age for Stelara for pediatric plaque psoriasis changed from 12 to 6
03/15/2021	Added Simponi Aria & Xeljanz to Polyarticular Juvenile Idiopathic Arthritis Updated age for Simponi Aria for Psoriatic Arthritis

Therapeutic Class: Behavioral Health Medications for Adults

Clinical Edit Number	Long Description
4110	Quantity limit edit that is applied to atypical antipsychotics for claims identified in the adult population
4125	Quantity limit edit that is applied to antidepressants for claims identified in the adult population
4140	Quantity limit edit that is applied to ADD/ADHD and stimulant medications for claims identified in the adult population
58610	Therapeutic duplication edit that is applied to atypical antipsychotics for claims identified in the adult population
58620	Therapeutic duplication edit that is applied to antidepressants for claims identified in the adult population
58630	Therapeutic duplication edit that is applied to antidepressants for claims identified in the adult population
58640	Therapeutic duplication edit that is applied to anxiolytics for claims identified in the adult population
4610	Quantity limit edit that is applied to behavioral health drugs except atypical antipsychotics, antidepressants, ADD/ADHD drugs and stimulants for claims identified in the adult population

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination****** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at EPSDT provider page: http://medicaid.ncdhhs.gov/

Criteria:

Clinical Edit 4110
Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the atypical antipsychotics listed in Appendix A will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved adult age ranges.
c. The quantity limits are restricted to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 4125
Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the antidepressants listed in Appendix B will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved adult age ranges.
c. The quantity limits are restricted to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 4140
Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the ADD/ADHD medications listed in Appendix C will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved adult age ranges.
c. The quantity limits are restricted to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 58610

Concomitant use of three or more atypical antipsychotics listed in Appendix D will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with three or more atypical antipsychotics.
b. The edit is applied to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 58620

Concomitant use of two or more antidepressants listed in Appendix E will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with two or more antidepressants in the same chemical class.
b. The edit is applied to the antidepressant chemical class; selective serotonin reuptake inhibitors (SSRIs) and includes combination products.
c. The edit is applied to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 58630

Concomitant use of two or more antidepressants listed in Appendix F will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with two or more antidepressants in the same chemical class.
b. The edit is applied to the antidepressant chemical class; serotonin-norepinephrine reuptake inhibitors (SNRIs).
c. The edit is applied to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 58640

Concomitant use of two or more anxiolytics listed in Appendix G will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with two or more anxiolytics.
b. The edit is applied to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Clinical Edit 4610

Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the behavioral health medications listed in Appendix H (does not include antidepressants, atypical antipsychotics, stimulants and ADD/ADHD medications) will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved adult age ranges.
c. The quantity limits are restricted to the adult population defined as beneficiaries greater than or equal to 18 years of age.

Resolution:

A Pharmacist may override the prior authorization edit at point-of-sale after consulting the prescriber to determine the clinical need for a quantity exceeding the FDA recommended maximum or therapeutic duplication of a behavioral health medication. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

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Note: Individual Drug Package Inserts may have also been accessed during edit development to obtain Food and Drug Administration full prescribing information.

APPENDIX A

Edit 4110 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the atypical antipsychotics.

GCN	Drug Description	Quantity	Days Supply
34284, 37681, 34285, 37682	ARIPIPRAZOLE 300 MG, 400 MG	1	30
18537, 18538, 18539, 18541, 44439, 44441, 44442, 44443	ARIPIPRAZOLE 10 MG, 15 MG, 20 MG, 30 MG	30	30
20173, 44438	ARIPIPRAZOLE 5 MG	45	30
26445, 26448, 26305, 44437	ARIPIPRAZOLE 10 MG, 15 MG, 2 MG	60	30
97696	ARIPIPRAZOLE 9.75MG/1.3	120	30
24062	ARIPIPRAZOLE 1 MG/ML	750	30
39726, 39727, 39728,	ARIPIPRAZOLE LAUROXIL 441MG/1.6ML, 662MG/2.4ML, 882MG/3.2ML	3.2	30
43488	ARIPIPRAZOLE LAUROXIL 1064MG/3.9ML	3.9	60
44941	ARIPIPRAZOLE LAUROXIL 675MG/2.4ML	2.4	30
27528, 21636, 38479	ASENAPINE MALEATE 10 MG, 5 MG, 2.5MG	60	30
47229, 47232, 47233	ASENAPINE TRANSDERMAL SYSTEM 3.8MG/24HRS, 5.7MG/24HRS, 7.6MG/24HRS	30	30
38278, 38476, 38589, 38609, 38618, 38619	BREXPIPRAZOLE 0.25 MG, 0.5MG, 1MG, 2MG, 3MG, 4MG	30	30
39579, 39582, 39583, 39584	CARIPRAZINE 1.5MG, 3MG, 4.5MG, 6MG	30	30
98791, 18141, 21784, 18143	CLOZAPINE 12.5 MG, 25 MG, 50 MG	90	30
28874, 31672	CLOZAPINE 200 MG	120	30
28873	CLOZAPINE 150 MG	150	30
18142, 21785	CLOZAPINE 100 MG	270	30
14336	CLOZAPINE 50 MG/ML	540	30
28034	ILOPERIDONE 1-2-4-6MG	8	4
28025, 28030, 28033, 28026, 28027, 28028, 28029	ILOPERIDONE 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG	60	30
47492	LUMATEPERONE TOSYLATE 42MG	30	30
33147, 31226, 29366, 35192	LURASIDONE HCL 120 MG, 20 MG, 40 MG, 60MG	30	30
29367	LURASIDONE HCL 80 MG	60	30
15082, 17407, 92008, 15085, 34022, 15084, 15086, 34023, 15083, 92007, 15081	OLANZAPINE 10 MG, 15 MG, 2.5 MG, 20 MG, 5 MG, 7.5 MG	30	30
27848	OLANZAPINE PAMOATE 405 MG	1	28
27855, 27849	OLANZAPINE PAMOATE 210 MG, 300 MG	2	28
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG	30	30

GCN	Drug Description	Quantity	Days Supply
27685, 97769, 97771	PALIPERIDONE 1.5 MG, 3 MG, 9 MG	30	30
97770	PALIPERIDONE 6 MG	60	30
27416, 27417, 27418, 27414, 27415	PALIPERIDONE PALMITATE 117MG/0.75ML, 156 MG/ML, 234MG/1.5ML, 39MG/0.25ML, 78MG/0.5ML	1.5	28
38697, 38698, 38699, 38702	PALIPERIDONE PALMITATE 273MG/0.875ML, 410MG/1.315ML, 546MG/1.75ML, 819MG/2.625ML	2.625	90
16193, 98522	QUETIAPINE FUMARATE 150 MG, 200 MG	30	30
67665, 98523, 26411, 98524, 98994	QUETIAPINE FUMARATE 300 MG, 400 MG, 50 MG	60	30
67662, 67663, 67661, 26409	QUETIAPINE FUMARATE 100 MG, 200 MG, 25 MG, 50 MG	90	30
24448, 92872, 19541, 92892, 16136, 19178, 16137, 19179, 16139, 25025	RISPERIDONE 0.25 MG, 0.5 MG, 1 MG, 2 MG, 4 MG	60	30
16138, 25024	RISPERIDONE 3 MG	120	30
16135, 35049, 35051, 35052	RISPERIDONE 1 MG/ML, 2 MG/2 ML, 3 MG/3 ML	360	30
98414, 20217, 20218, 20219	RISPERIDONE MICROSPHERES 12.5MG/2ML, 25 MG/2 ML, 37.5MG/2ML, 50 MG/2 ML	2	28
45127, 45128	RISPERIDONE ER 90MG SYRINGE KIT, ER 120MG SYRING KIT	1	30
13331, 13332, 13333, 13334	ZIPRASIDONE HCL 20 MG, 40 MG, 60 MG, 80 MG	60	30
17037	ZIPRASIDONE MESYLATE FNL 20MG/1	60	30

APPENDIX B

Edit 4125 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the antidepressants.

GCN	Drug Description	Quantity	Days Supply
26198, 16996, 17050	BUPROPION HBR 174MG, 348MG, 522MG	30	30
20317, 20318, 33081	BUPROPION HCL 150 MG, 300 MG, 450 MG	30	30
16387, 16386, 17573	BUPROPION HCL 100 MG, 150 MG, 200 MG	60	30
16385	BUPROPION HCL 100 MG	120	30
16384	BUPROPION HCL 75 MG	180	30
16343	CITALOPRAM HYDROBROMIDE 40 MG	30	30
16345, 16342	CITALOPRAM HYDROBROMIDE 10 MG, 20 MG	45	30
16344, 34671	CITALOPRAM HYDROBROMIDE 10 MG/5 ML, 20 MG/10ML	600	30
34482, 35584, 34470, 35582	DESVENLAFAXINE 100 MG, 50 MG	30	30
36273, 36272	DESVENLAFAXINE FUMARATE 100 MG, 50 MG	30	30
99452, 99451	DESVENLAFAXINE SUCCINATE 100 MG, 50 MG	30	30
23161, 23164	DULOXETINE HCL 20 MG, 60 MG	60	30
23162	DULOXETINE HCL 30 MG	90	30
17851, 17987, 18975	ESCITALOPRAM OXALATE 10 MG, 20 MG, 5 MG	30	30
19035	ESCITALOPRAM OXALATE 5 MG/5 ML	600	30
12929	FLUOXETINE HCL 90 MG	4	28
30817	FLUOXETINE HCL 60 MG	30	30
16355	FLUOXETINE HCL 40 MG	60	30
16353, 16356, 16354, 16359	FLUOXETINE HCL 10 MG, 20 MG	90	30
16357	FLUOXETINE HCL 20 MG/5 ML	600	30
99481, 99482	FLUVOXAMINE MALEATE 100 MG, 150 MG	60	30
16349, 16347, 16348	FLUVOXAMINE MALEATE 100 MG, 25 MG, 50 MG	90	30
35335	LEVOMILNACIPRAN HYDROCHLORIDE 20-40MG	28	28
35334, 35327, 35328, 35329	LEVOMILNACIPRAN HYDROCHLORIDE 120 MG, 20 MG, 40 MG, 80 MG	30	30
22025	MILNACIPRAN HCL 12.5-25-50	55	180
22022, 21979, 22008, 22019	MILNACIPRAN HCL 100 MG, 12.5 MG, 25 MG, 50 MG	60	30
12529, 16732, 12531, 16733, 13041, 16734, 21817	MIRTAZAPINE 15 MG, 30 MG, 45 MG, 7.5 MG	30	30
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG,	30	30

GCN	Drug Description	Quantity	Days Supply
	6MG-50MG		
16364, 17078, 16366, 16368	PAROXETINE HCL 10 MG, 12.5 MG, 20 MG, 40 MG	30	30
17077, 16367, 17079	PAROXETINE HCL 25 MG, 30 MG, 37.5 MG	60	30
16369	PAROXETINE HCL 10 MG/5 ML	900	30
20854, 20855, 20857	PAROXETINE MESYLATE 10 MG, 20 MG, 40 MG	30	30
20856	PAROXETINE MESYLATE 30 MG	60	30
26614, 26612, 26613	SELEGILINE 12MG/24HR, 6 MG/24 HR, 9 MG/24 HR	30	30
16373, 16374	SERTRALINE HCL 25 MG, 50 MG	45	30
16375	SERTRALINE HCL 100 MG	60	30
16376	SERTRALINE HCL 20 MG/ML	300	30
14353, 16818, 14354, 14349, 16816	VENLAFAXINE HCL 150 MG, 225 MG, 37.5 MG	30	30
16815, 16811, 16812, 16813, 14352, 16817	VENLAFAXINE HCL 100 MG, 25 MG, 37.5 MG, 50 MG, 75 MG	90	30
16814	VENLAFAXINE HCL 75 MG	150	30
29916, 31956, 29917, 29918	VILAZODONE HYDROCHLORIDE 10 MG, 10-20-40MG, 20 MG, 40 MG	30	30
35347, 35349, 35346	VORTIOXETINE HYDROBROMIDE 10 MG, 20 MG, 5 MG	30	30

APPENDIX C

Edit 4140 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the ADD/ADHD medications.

GCN	Drug Description	Quantity	Days Supply
19822	AMPHETAMINE SULFATE 5 MG	90	30
19821	AMPHETAMINE SULFATE 10 MG	180	30
26539, 18779, 18781, 26538	ATOMOXETINE HCL 100 MG, 40 MG, 60 MG, 80 MG	30	30
18776, 18778	ATOMOXETINE HCL 10 MG, 25 MG	60	30
18777	ATOMOXETINE HCL 18 MG	90	30
33007	CLONIDINE HCL 0.1-0.2 MG	60	30
29319	CLONIDINE HCL 0.1 MG	120	30
24734, 97111, 24735, 30305, 28035, 30306, 28933, 24733	DEXMETHYLPHENIDATE HCL 10 MG, 15 MG, 20 MG, 25 MG, 30 MG, 35 MG, 40 MG, 5 MG	30	30
14975, 14973, 14974	DEXMETHYLPHENIDATE HCL 10 MG, 2.5 MG, 5 MG	60	30
19885, 34734, 36463, 36464, 19852, 19881	DEXTROAMPHETAMINE SULFATE 15 MG, 2.5 MG, 20 MG, 30 MG, 5 MG	60	30
19850, 19851, 34735	DEXTROAMPHETAMINE SULFATE 10 MG, 15 MG, 7.5 MG	120	30
19880	DEXTROAMPHETAMINE SULFATE 10 MG	180	30
99801	DEXTROAMPHETAMINE SULFATE 5 MG/5 ML	1800	30
14635, 17468, 14636, 17469, 14637, 17459	DEXTROAMPHETAMINE/AMPHETAMINE 10 MG, 15 MG, 20 MG, 25 MG, 30 MG, 5 MG	30	30
56973, 56972	DEXTROAMPHETAMINE/AMPHETAMINE 20 MG, 30 MG	60	30
56971, 29008, 29009, 56970, 29007	DEXTROAMPHETAMINE/AMPHETAMINE 10 MG, 12.5 MG, 15 MG, 5 MG, 7.5 MG	90	30
27576, 27578, 27579, 27582	GUANFACINE HCL 1 MG, 2 MG, 3 MG, 4 MG	30	30
37674, 99366, 98071, 99367, 98072, 99368, 98073	LISDEXAMFETAMINE DIMESYLATE 10 MG, 20 MG, 30 MG, 40 MG, 50 MG, 60 MG, 70 MG	30	30
19932	METHAMPHETAMINE HCL 5 MG	150	30
26801, 26802, 26803, 26804	METHYLPHENIDATE 10MG/9HR, 15MG/9HR, 20 MG/9 HR, 30MG/9HR	30	30
20384, 21763, 12567, 20385, 20387, 17123, 20386, 20391, 26734, 26735, 12248, 26736	METHYLPHENIDATE HCL 10 MG, 18 MG, 20 MG, 27 MG, 30 MG, 40 MG, 50 MG, 54 MG, 60 MG	30	30
20388, 12568	METHYLPHENIDATE HCL 30 MG, 36 MG	60	30
15911, 93075, 22682, 15920, 16180, 15913, 22683	METHYLPHENIDATE HCL 10 MG, 2.5 MG, 20 MG, 5 MG	90	30
22684	METHYLPHENIDATE HCL 10 MG	180	30
33887	METHYLPHENIDATE HCL 5 MG/ML	360	30

22685	METHYLPHENIDATE HCL 5 MG/5 ML	450	30
22686	METHYLPHENIDATE HCL 10 MG/5 ML	900	30
97234, 97235, 97236, 97237, 97238, 97239, 97240	METHYLPHENIDATE HCL XR 10MG, 15MG, 20MG, 30MG, 40MG, 50MG, 60MG	30	30

APPENDIX D

Edit 58610 - Concomitant use of three or more atypical antipsychotics.

GCN	Drug Description
24062, 18537, 26445, 18538, 26448, 26305, 18539, 18541, 34284, 37681, 34285, 37682, 20173, 97696, 44437, 44438, 44439, 44441, 44442, 44443	ARIPIPRAZOLE 1 MG/ML, 10 MG, 15 MG, 2 MG, 20 MG, 30 MG, 300 MG, 400 MG, 5 MG, 9.75MG/1.3
39726, 39727, 39728, 43488	ARIPIPRAZOLE LAUROXIL 441MG/1.6ML, 662MG/2.4ML, 882MG/,3.2ML, 1064MG/3.9ML
44941	ARIPIPRAZOLE LAUROXIL 675MG/2.4ML
27528, 38479, 21636	ASENAPINE MALEATE 10 MG, 2.5 MG, 5 MG
47229, 47232, 47233	ASENAPINE TRANSDERMAL SYSTEM 3.8MG/24HRS, 5.7MG/24HRS, 7.6MG/24HRS
38278, 38476, 38589, 38609, 38618, 38619	BREXPIPRAZOLE 0.25 MG, 0.5MG, 1MG, 2MG, 3MG, 4MG
39579, 39582, 39583, 39584	CARIPRAZINE 1.5MG, 3MG, 4.5MG, 6MG
18142, 21785, 98791, 28873, 28874, 31672, 18141, 21784, 18143, 14336	CLOZAPINE 100 MG, 12.5 MG, 150 MG, 200 MG, 25 MG, 50 MG, 50 MG/ML
28025, 28030, 28033, 28034, 28026, 28027, 28028, 28029	ILOPERIDONE 1 MG, 10 MG, 12 MG, 1-2-4-6MG, 2 MG, 4 MG, 6 MG, 8 MG
47492	LUMATEPERONE TOSYLATE 42MG
33147, 31226, 29366, 35192, 29367	LURASIDONE HCL 120 MG, 20 MG, 40 MG, 60 MG, 80 MG
15082, 17407, 92008, 15085, 34022, 15084, 15086, 34023, 15083, 92007, 15081	OLANZAPINE 10 MG, 15 MG, 2.5 MG, 20 MG, 5 MG, 7.5 MG
27855, 27849, 27848	OLANZAPINE PAMOATE 210 MG, 300 MG, 405 MG
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG
27685, 97769, 97770, 97771	PALIPERIDONE 1.5 MG, 3 MG, 6 MG, 9 MG
27416, 27417, 27418, 38697, 27414, 38698, 38699, 27415, 38702	PALIPERIDONE PALMITATE 117MG/0.75ML, 156 MG/ML, 234MG/1.5ML, 273MG/.875ML, 39MG/0.25ML, 410/1.315ML, 546MG/1.75ML, 78MG/0.5ML, 819/2.625ML
67662, 16193, 67663, 98522, 67661, 67665, 98523, 26411, 98524, 26409, 98994	QUETIAPINE FUMARATE 100 MG, 150 MG, 200 MG, 25 MG, 300 MG, 400 MG, 50 MG
24448, 92872, 19541, 92892, 16136, 19178, 16135, 35049, 16137, 19179, 35051, 16138, 25024, 35052, 16139, 25025, 45127, 45128	RISPERIDONE 0.25 MG, 0.5 MG, 1 MG, 1 MG/ML, 2 MG, 2 MG/2 ML, 3 MG, 3 MG/3 ML, 4 MG, ER 90MG SYRINGE KIT, ER 120MG SYRING KIT
98414, 20217, 20218, 20219	RISPERIDONE MICROSPHERES 12.5MG/2ML, 25 MG/2 ML, 37.5MG/2ML, 50 MG/2 ML
13331, 13332, 13333, 13334	ZIPRASIDONE HCL 20 MG, 40 MG, 60 MG, 80 MG
17037	ZIPRASIDONE MESYLATE FNL 20MG/1

APPENDIX E

Edit 58620 - Concomitant use of two or more antidepressants (SSRIs).

GCN	Drug Description
16345, 16344, 16342, 34671, 16343	CITALOPRAM HYDROBROMIDE 10 MG, 10 MG/5 ML, 20 MG, 20 MG/10ML, 40 MG
17851, 17987, 18975, 19035	ESCITALOPRAM OXALATE 10 MG, 20 MG, 5 MG, 5 MG/5 ML
16353, 16356, 16354, 16359, 16357, 16355, 30817, 12929	FLUOXETINE HCL 10 MG, 20 MG, 20 MG/5 ML, 40 MG, 60 MG, 90 MG
16349, 99481, 99482, 16347, 16348	FLUVOXAMINE MALEATE 100 MG, 150 MG, 25 MG, 50 MG
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG
16364, 16369, 17078, 16366, 17077, 16367, 17079, 16368	PAROXETINE HCL 10 MG, 10 MG/5 ML, 12.5 MG, 20 MG, 25 MG, 30 MG, 37.5 MG, 40 MG
20854, 20855, 20856, 20857	PAROXETINE MESYLATE 10 MG, 20 MG, 30 MG, 40 MG
16375, 16376, 16373, 16374	SERTRALINE HCL 100 MG, 20 MG/ML, 25 MG, 50 MG
29916, 31956, 29917, 29918	VILAZODONE HYDROCHLORIDE 10 MG, 10-20-40MG, 20 MG, 40 MG

APPENDIX F

Edit 58630 - Concomitant use of two or more antidepressants (SNRIs).

GCN	Drug Description
34482, 35584, 34470, 35582	DESVENLAFAXINE 100 MG, 50 MG
36273, 36272	DESVENLAFAXINE FUMARATE 100 MG, 50 MG
99452, 38222, 99451	DESVENLAFAXINE SUCCINATE 100 MG, 25 MG, 50 MG
23161, 23162, 38728, 23164	DULOXETINE HCL 20 MG, 30 MG, 40 MG, 60 MG
35334, 35327, 35335, 35328, 35329	LEVOMILNACIPRAN HYDROCHLORIDE 120 MG, 20 MG, 20-40MG, 40 MG, 80 MG
22022, 21979, 22025, 22008, 22019	MILNACIPRAN HCL 100 MG, 12.5 MG, 12.5-25-50, 25 MG, 50 MG
16815, 14353, 16818, 14354, 16811, 14349, 16812, 16816, 16813, 14352, 16814, 16817	VENLAFAXINE HCL 100 MG, 150 MG, 225 MG, 25 MG, 37.5 MG, 50 MG, 75 MG

APPENDIX G

Edit 58640 - Concomitant use of two or more anxiolytics.

GCN	Drug Description
14260, 24368, 14261, 17423, 24369, 14262, 17424, 24373, 14264, 14263, 17425, 24374, 19681	ALPRAZOLAM 0.25 MG, 0.5 MG, 1 MG, 1 MG/ML, 2 MG, 3 MG
14031, 14032, 14033	CHLORDIAZEPOXIDE HCL 10 MG, 25 MG, 5 MG
14090, 14092, 14093	CLORAZEPATE DIPOTASSIUM 15 MG, 3.75 MG, 7.5 MG
14220, 14221, 14222, 31551, 45560, 14200, 14210, 45500	DIAZEPAM 10 MG, 2 MG, 5 MG, 5 MG/5 ML, 5 MG/ML
14140, 14150, 19601, 14141, 14151	LORAZEPAM 2 MG/ML, 4 MG/ML
13801, 13802	MEPROBAMATE 200 MG, 400 MG
14230, 14231, 14232	OXAZEPAM 10 MG, 15 MG, 30 MG

APPENDIX H

Edit 4610 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the behavioral health medications (does not include antidepressants, atypical antipsychotics, stimulants and ADD/ADHD medications).

GCN	Drug Description	Quantity	Days Supply
17423, 17424, 17425, 19681	ALPRAZOLAM 0.5 MG, 1 MG, 2 MG, 3 MG	60	30
24368, 24369, 24373, 14263, 24374	ALPRAZOLAM 0.25 MG, 0.5 MG, 1 MG, 2 MG	90	30
14260, 14261, 14262, 14264	ALPRAZOLAM 0.25 MG, 0.5 MG, 1 MG, 1 MG/ML	180	30
16683, 16684	AMITRIP HCL/CHLORDIAZEPOXIDE 12.5MG-5MG, 25 MG-10MG	180	30
98590, 36082, 98592, 98591	ARMODAFINIL 150 MG, 200 MG, 250 MG, 50 MG	30	30
64672	BUPRENORPHINE HCL 2 MG	90	30
64673	BUPRENORPHINE HCL 8 MG	60	30
44187	BUPRENORPHINE XR 100MG/0.5ML	0.5ML	30
44186	BUPRENORPHINE XR 300MG/1.5ML	1.5ML	30
33744, 37823	BUPRENORPHINE HCL/NALOXONE HCL 12 MG-3 MG, 8.6-2.1 MG	30	30
33741	BUPRENORPHINE HCL/NALOXONE HCL 4MG-1MG	30	30
34905, 18974, 28959	BUPRENORPHINE HCL/NALOXONE HCL 5.7-1.4 MG, 8 MG-2 MG	60	30
39394	BUPRENORPHINE HCL/NALOXONE HCL 2.9-0.71mg	30	30
37824	BUPRENORPHINE HCL/NALOXONE HCL 11.4-2.9mg	30	30
36677, 36678	BUPRENORPHINE / NALOXONE 2.1-0.3mg, 4.2-0.7mg	60	30
36679	BUPRENORPHINE / NALOXONE 6.3-1mg	30	30
34904, 18973, 28958	BUPRENORPHINE HCL/NALOXONE HCL 1.4-0.36MG, 2 MG-0.5MG	90	30
42843	BUPRENORPHINE / NALOXONE 0.7-0.18	30	30
14031, 14032, 14033	CHLORDIAZEPOXIDE HCL 10 MG, 25 MG, 5 MG	360	30
19467, 19468, 17470, 19469, 17471, 19470	CLONAZEPAM 0.125 MG, 0.25 MG, 0.5 MG, 1 MG	180	30
17472, 19472	CLONAZEPAM 2 MG	300	30
14090, 14092, 14093	CLORAZEPATE DIPOTASSIUM 15 MG, 3.75 MG, 7.5 MG	180	30
29290	DEXTROMETHORPHAN HBR/QUINIDINE 20 MG-10MG	60	30
14220	DIAZEPAM 10 MG	120	30

GCN	Drug Description	Quantity	Days Supply
14222	DIAZEPAM 5 MG	180	30
14221, 45500	DIAZEPAM 2 MG, 5 MG/ML	240	30
31551, 45560	DIAZEPAM 5 MG/5 ML	1200	30
14160, 14161	LORAZEPAM 0.5 MG, 1 MG	90	30
14162, 19601	LORAZEPAM 2 MG, 2 MG/ML	150	30
26101, 26102	MODAFINIL 100 MG, 200 MG	30	30
27095	NALTREXONE MICROSPHERES 380MG	1	28
14231, 14232	OXAZEPAM 15 MG, 30 MG	120	30
14230	OXAZEPAM 10 MG	240	30
18104	SODIUM OXYBATE 500 MG/ML	675	30

Criteria Change Log	
May 1, 2017	Criteria effective date
July 20, 2017 – July 5, 2017	Repost for Appendix Updates Appendix A – added GCN, drug description, quantity days supply for: aripiprazole lauroxil, asenapine 2.5mg, brexpiprazole, cariprazine, olanzapine, paliperidone palmitate; lurasidone 60mg quantity changed to 30 Appendix B - GCN 16385 duplication deleted Appendix D - added GCN, drug description, quantity, days supply for: aripiprazole lauroxil, brexpiprazole, cariprazine
July 6, 2017	No public comments to policy Appendix updates
July 11, 2017	All appendix updates incorporated in policy
December 4, 2018	Appendix C added GCNs for methylphenidate XR – 97234, 97235, 97236, 97237, 97238, 97239, 97240
December 4, 2018	Appendix H changed GCN 64673 to quantity 60
December 4, 2018	Appendix H added GCNs 44186, 44187
December 4, 2018	Appendix H changed GCN 33741 to quantity 30
December 4, 2018	Appendix H added GCNs 39394, 37824, 36677,36678, 36679, 42843
December 4, 2018	Changed edit numbers 4410 to 58610; 4420 to 58620; 4421 to 58630; 4440 to 58640
July 1, 2019	Add GCN 45127, 45128, 44941 to Appendix A and D
July 1, 2019	Add GCN 44437, 44438, 44439, 44441, 44442, 44443 to Appendix A and D
July 1, 2019	Add GCN 46077, 46078 and 46079 to Appendix H
December 16, 2019	Remove GCN 46077, 46078, 46079 from Appendix H
April 1, 2021	Add GCN 47492 to Appendix A and Appendix D
April 1, 2021	Add GCNs 47229, 47232, 47233 to Appendix A and Appendix D
April 1, 2021	Add edit descriptions to Appendix A through Appendix H.

WellCare of North Carolina
Prior Authorization Criteria
Behavioral Health - Pediatric

Effective Date: May 1, 2017
Amended Date: April 1, 2021

Therapeutic Class: Behavioral Health Medications for Pediatrics

Clinical Edit Number	Long Description
7110	Quantity limit edit that is applied to atypical antipsychotics for claims identified in the pediatric population
7125	Quantity limit edit that is applied to antidepressants for claims identified in the pediatric population
7140	Quantity limit edit that is applied to ADD/ADHD and stimulant medications for claims identified in the pediatric population
58650	Therapeutic duplication edit that is applied to atypical antipsychotics for claims identified in the pediatric population
58660	Therapeutic duplication edit that is applied to antidepressants for claims identified in the pediatric population
58670	Therapeutic duplication edit that is applied to antidepressants for claims identified in the pediatric population
58680	Therapeutic duplication edit that is applied to anxiolytics for claims identified in the pediatric population
7610	Quantity limit edit that is applied to all behavioral health drugs except atypical antipsychotics, antidepressants, ADD/ADHD drugs and stimulants for claims identified in the pediatric population

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination****** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at EPSDT provider page: to https://medicaid.ncdhhs.gov

Criteria:

Clinical Edit 7110
Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the atypical antipsychotics listed in Appendix A will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved pediatric age ranges.
c. The quantity limits are restricted to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 7125
Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the antidepressants listed in Appendix B will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved pediatric age ranges.
c. The quantity limits are restricted to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 7140
Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the ADD/ADHD medications listed in Appendix C will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved pediatric age ranges.
c. The quantity limits are restricted to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 58650

Concomitant use of three or more atypical antipsychotics listed in Appendix D will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with three or more atypical antipsychotics.
b. The edit is applied to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 58660

Concomitant use of two or more antidepressants listed in Appendix E will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with two or more antidepressants in the same chemical class.
b. The edit is applied to the antidepressant chemical class selective serotonin reuptake inhibitors (SSRIs) and includes combination products.
c. The edit is applied to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 58670

Concomitant use of two or more antidepressants listed in Appendix F will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with two or more antidepressants in the same chemical class.
b. The edit is applied to the antidepressant chemical class serotonin-norepinephrine reuptake inhibitors (SNRIs).
c. The edit is applied to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 58680

Concomitant use of two or more anxiolytics listed in Appendix G will be denied.

a. The edit is applied based on 60 or more days of overlapping therapy with two or more anxiolytics.
b. The edit is applied to the pediatric population defined as beneficiaries less than 18 years of age.

Clinical Edit 7610

Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the behavioral health medications listed in Appendix H (does not include antidepressants, atypical antipsychotics, stimulants and ADD/ADHD medications) will be denied.

a. The quantity limits are applied based on the maximum daily doses approved by the FDA.
b. The quantity limits are based on FDA approved pediatric age ranges.
c. The quantity limits are restricted to the pediatric population defined as beneficiaries less than 18 years of age.

Resolution:

A Pharmacist may override the prior authorization edit at point-of-sale after consulting the prescriber to determine the clinical need for a quantity exceeding the FDA recommended maximum or therapeutic duplication of a behavioral health medication. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

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Note: Individual Drug Package Inserts may have also been accessed during edit development to obtain Food and Drug Administration full prescribing information.

APPENDIX A

Edit 7110 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the atypical antipsychotics.

GCN	Drug Description	Quantity	Days Supply
34284, 37681, 34285, 37682	ARIPIPRAZOLE 300 MG, 400 MG	1	30
18537, 26445, 18538, 26448, 18539, 18541, 44439, 44441, 44442, 44443	ARIPIPRAZOLE 10MG, 15MG, 20MG, 30MG	30	30
20173, 44438	ARIPIPRAZOLE 5 MG	45	30
26305, 44437	ARIPIPRAZOLE 2 MG	60	30
97696	ARIPIPRAZOLE 9.75MG/1.3	120	30
24062	ARIPIPRAZOLE 1 MG/ML	750	30
39726, 39727, 39728	ARIPIPRAZOLE LAUROXIL 441MG/1.6ML, 662MG/2.4ML, 882MG/3.2ML,	3.2	30
43488	ARIPIPRAZOLE LAUROXIL 1064MG/3.9ML	3.9	60
44941	ARIPIPRAZOLE LAUROXIL 675mg/2.4ml	2.4	30
27528, 21636, 38479	ASENAPINE MALEATE 10 MG, 5 MG, 2.5MG	60	30
47229, 47232, 47233	ASENAPINE TRANSDERMAL SYSTEM 3.8MG/24HRS, 5.7MG/24HRS, 7.6MG/24HRS	30	30
38278, 38476, 38589, 38609, 38618, 38619	BREXPIPRAZOLE 0.25 MG, 0.5MG, 1MG, 2MG, 3MG, 4MG	30	30
39579, 39582, 39583, 39584	CARIPRAZINE 1.5MG, 3MG, 4.5MG, 6MG	30	30
98791, 18141, 21784, 18143	CLOZAPINE 12.5 MG, 25 MG, 50 MG	90	30
28874, 31672	CLOZAPINE 200 MG	120	30
28873	CLOZAPINE 150 MG	150	30
18142, 21785	CLOZAPINE 100 MG	270	30
14336	CLOZAPINE 50 MG/ML	540	30
28034	ILOPERIDONE 1-2-4-6MG	8	4
28030, 28033, 28026, 28027, 28028, 28029	ILOPERIDONE 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG	60	30
28025	ILOPERIDONE 1 MG	90	30
47492	LUMATEPERONE TOSYLATE 42MG	30	30
33147, 31226, 29366, 35192	LURASIDONE HCL 120 MG, 20 MG, 40 MG, 60MG	30	30
29367	LURASIDONE HCL 80 MG	60	30
15082, 17407, 92008, 15085, 34022, 15084, 15086, 34023, 15083, 92007, 15081	OLANZAPINE 10 MG, 15 MG, 2.5 MG, 20 MG, 5 MG, 7.5 MG	30	30
27855, 27849, 27848	OLANZAPINE PAMOATE 210MG, 300MG, 405MG	0.08	28

GCN	Drug Description	Quantity	Days Supply
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG	30	30
97769, 97771	PALIPERIDONE 3 MG, 9 MG	30	30
97770	PALIPERIDONE 6 MG	60	30
27685	PALIPERIDONE 1.5 MG	90	30
27416, 27417, 27418, 27414, 27415	PALIPERIDONE PALMITATE 117MG/0.75, 156 MG/ML, 234MG/1.5, 39MG/0.25, 78MG/0.5ML	1.5	28
38697, 38698, 38699, 38702	PALIPERIDONE PALMITATE 273MG/0.875ML, 410MG/1.315ML, 546MG/1.75ML, 819MG/2.625ML	2.625	90
98522	QUETIAPINE FUMARATE 200 MG	30	30
67665, 98523, 26411, 98524	QUETIAPINE FUMARATE 300 MG, 400 MG	60	30
67662, 67663, 26409	QUETIAPINE FUMARATE 100MG, 200MG, 50MG	90	30
16193, 98994	QUETIAPINE FUMARATE 150 MG, 50 MG	150	30
67661	QUETIAPINE FUMARATE 25 MG	180	30
24448, 92872, 19541, 92892, 16136, 19178, 16137, 19179, 16138, 25024,	RISPERIDONE 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG	60	30
16139, 25025	RISPERIDONE 4MG	30	30
16135, 35049, 35051, 35052	RISPERIDONE 1 MG/ML, 2 MG/2ML, 3MG/3ML	360	30
98414, 20217, 20218, 20219	RISPERIDONE MICROSPHERES 12.5MG/2ML, 25 MG/2ML, 37.5MG/2ML, 50MG/2ML	2	28
45127, 45128	RISPERIDONE ER 90MG SYRINGE KIT; ER 120MG SYRINGE KIT	1	30
13331, 13332, 13333, 13334	ZIPRASIDONE HCL 20MG, 40MG, 60MG, 80MG	60	30
17037	ZIPRASIDONE MESYLATE FNL 20MG/1	60	30

APPENDIX B

Edit 7125 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the antidepressants.

GCN	Drug Description	Quantity	Days Supply
26198, 16996, 17050	BUPROPION HBR 174MG, 348MG, 522MG	30	30
20317, 20318, 33081	BUPROPION HCL 150 MG, 300 MG, 450 MG	30	30
16387, 16386, 17573	BUPROPION HCL 100 MG, 150 MG, 200 MG	60	30
16385	BUPROPION HCL 100 MG	120	30
16384	BUPROPION HCL 75 MG	180	30
16343	CITALOPRAM HYDROBROMIDE 40 MG	30	30
16345, 16342	CITALOPRAM HYDROBROMIDE 10 MG, 20 MG	45	30
16344, 34671	CITALOPRAM HYDROBROMIDE 10 MG/5ML, 20MG/10ML	600	30
34482, 35584, 34470, 35582	DESVENLAFAXINE 100 MG, 50 MG	30	30
36273, 36272	DESVENLAFAXINE FUMARATE 100 MG, 50 MG	30	30
99452, 99451	DESVENLAFAXINE SUCCINATE 100 MG, 50 MG	30	30
23162, 23164	DULOXETINE HCL 30 MG, 60 MG	30	30
23161	DULOXETINE HCL 20 MG	60	30
17851, 17987, 18975	ESCITALOPRAM OXALATE 10 MG, 20 MG, 5 MG	30	30
19035	ESCITALOPRAM OXALATE 5 MG/5 ML	600	30
12929	FLUOXETINE HCL 90 MG	4	28
16355, 30817	FLUOXETINE HCL 40 MG, 60 MG	30	30
16353, 16356, 16354, 16359	FLUOXETINE HCL 10 MG, 20 MG	90	30
16357	FLUOXETINE HCL 20 MG/5 ML	450	30
16349, 99481, 99482	FLUVOXAMINE MALEATE 100 MG, 150 MG	60	30
16347, 16348	FLUVOXAMINE MALEATE 25 MG, 50 MG	90	30
35335	LEVOMILNACIPRAN HYDROCHLORIDE 20-40MG	28	28
35334, 35327, 35328, 35329	LEVOMILNACIPRAN HYDROCHLORIDE 120 MG, 20 MG, 40 MG, 80 MG	30	30
22025	MILNACIPRAN HCL 12.5-25-50	55	180
22022, 21979, 22008, 22019	MILNACIPRAN HCL 100MG, 12.5MG, 25MG, 50MG	60	30
12529, 16732, 12531, 16733, 13041, 16734, 21817	MIRTAZAPINE 15 MG, 30 MG, 45 MG, 7.5 MG	30	30
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG	30	30
16364, 17078, 16366, 16368	PAROXETINE HCL 10 MG, 12.5 MG, 20 MG, 40 MG	30	30
17077, 16367, 17079	PAROXETINE HCL 25 MG, 30 MG, 37.5 MG	60	30
16369	PAROXETINE HCL 10 MG/5 ML	750	30
20854, 20855, 20857	PAROXETINE MESYLATE 10 MG, 20 MG, 40 MG	30	30
20856	PAROXETINE MESYLATE 30 MG	60	30

GCN	Drug Description	Quantity	Days Supply
26614, 26612, 26613	SELEGILINE 12MG/24HR, 6 MG/24 HR, 9 MG/24 HR	30	30
16373, 16374	SERTRALINE HCL 25 MG, 50 MG	45	30
16375	SERTRALINE HCL 100 MG	60	30
16376	SERTRALINE HCL 20 MG/ML	300	30
14353, 16818, 14354, 14349, 16816, 14352	VENLAFAXINE HCL 150 MG, 225 MG, 37.5 MG, 75 MG	30	30
16815, 16811, 16812, 16813, 16817	VENLAFAXINE HCL 100 MG, 25 MG, 37.5 MG, 50 MG, 75 MG	90	30
16814	VENLAFAXINE HCL 75 MG	120	30
29916, 31956, 29917, 29918	VILAZODONE HYDROCHLORIDE 10 MG, 10-20-40MG, 20 MG, 40 MG	30	30
35347, 35349, 35346	VORTIOXETINE HYDROBROMIDE 10 MG, 20 MG, 5 MG	30	30

APPENDIX C

Edit 7140 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the ADD/ADHD medications.

GCN	Drug Description	Quantity	Days Supply
19822	AMPHETAMINE SULFATE 5 MG	90	30
19821	AMPHETAMINE SULFATE 10 MG	180	30
26539, 18779, 18781, 26538	ATOMOXETINE HCL 100 MG, 40 MG, 60 MG, 80 MG	30	30
18776, 18778	ATOMOXETINE HCL 10 MG, 25 MG	60	30
18777	ATOMOXETINE HCL 18 MG	90	30
33007	CLONIDINE HCL 0.1-0.2 MG	60	30
29319	CLONIDINE HCL 0.1 MG	120	30
24734, 97111, 24735, 30305, 28035, 30306, 28933, 24733	DEXMETHYLPHENIDATE HCL 10 MG, 15 MG, 20 MG, 25 MG, 30 MG, 35 MG, 40 MG, 5 MG	30	30
14975, 14973, 14974	DEXMETHYLPHENIDATE HCL 10 MG, 2.5 MG, 5 MG	60	30
19885, 36463, 36464	DEXTROAMPHETAMINE SULFATE 15 MG, 20 MG, 30 MG	30	30
34734, 19852	DEXTROAMPHETAMINE SULFATE 2.5 MG, 5 MG	60	30
19850, 19851, 34735	DEXTROAMPHETAMINE SULFATE 10 MG, 15 MG, 7.5 MG	120	30
19880, 19881	DEXTROAMPHETAMINE SULFATE 10 MG, 5 MG	180	30
99801	DEXTROAMPHETAMINE SULFATE 5 MG/5 ML	1,800	30
14635, 17468, 14636, 17469, 14637, 56972, 17459	DEXTROAMPHETAMINE/AMPHETAMINE 10MG, 15MG, 20MG, 25MG, 30MG, 5MG	30	30
56973	DEXTROAMPHETAMINE/AMPHETAMINE 20 MG	60	30
56971, 29008, 29009, 56970, 29007	DEXTROAMPHETAMINE/AMPHETAMINE 10 MG, 12.5 MG, 15 MG, 5 MG, 7.5 MG	90	30
27576, 27578, 27579, 27582	GUANFACINE HCL 1MG, 2MG, 3MG, 4MG	30	30
37674, 99366, 98071, 99367, 98072, 99368, 98073	LISDEXAMFETAMINE DIMESYLATE 10 MG, 20 MG, 30 MG, 40 MG, 50 MG, 60 MG, 70 MG	30	30
19932	METHAMPHETAMINE HCL 5 MG	150	30
26801, 26802, 26803, 26804	METHYLPHENIDATE 10MG/9HR, 15MG/9HR, 20 MG/9 HR, 30MG/9HR	30	30
20384, 21763, 12567, 20385, 20387, 17123, 20386, 20391, 26734, 26735, 12248, 26736	METHYLPHENIDATE HCL 10 MG, 18 MG, 20 MG, 27 MG, 30 MG, 40 MG, 50 MG, 54 MG, 60 MG	30	30
20388, 12568	METHYLPHENIDATE HCL 30 MG, 36 MG	60	30

GCN	Drug Description	Quantity	Days Supply
15911, 93075, 22682, 15920, 16180, 15913, 22683	METHYLPHENIDATE HCL 10 MG, 2.5 MG, 20 MG, 5 MG	90	30
22684	METHYLPHENIDATE HCL 10 MG	180	30
33887	METHYLPHENIDATE HCL 5 MG/ML	360	30
22685	METHYLPHENIDATE HCL 5 MG/5 ML	450	30
22686	METHYLPHENIDATE HCL 10 MG/5 ML	900	30
97234, 97235, 97236, 97237, 97238, 97239, 97240	METHYLPHENIDATE HCL XR 10MG, 15MG, 20MG, 30MG, 40MG, 50MG, 60MG	30	30

APPENDIX D

Edit 58650 - Concomitant use of three or more atypical antipsychotics.

GCN	Drug Description
24062, 18537, 26445, 18538, 26448, 26305, 18539, 18541, 34284, 37681, 34285, 37682, 20173, 97696, 44437, 44438, 44439, 44441, 44442, 44443	ARIPIPRAZOLE 1 MG/ML, 10 MG, 15 MG, 2 MG, 20 MG, 30 MG, 300 MG, 400 MG, 5 MG, 9.75MG/1.3
39726, 39727, 39728, 43488	ARIPIPRAZOLE LAUROXIL 441MG/1.6ML, 662MG/2.4ML, 882MG/,3.2ML, 1064MG/3.9ML
44941	ARIPIPRAZOLE LAUROXIL 675MG/2.4ML
27528, 38479, 21636	ASENAPINE MALEATE 10 MG, 2.5 MG, 5 MG
47229, 47232, 47233	ASENAPINE TRANSDERMAL SYSTEM 3.8MG/24HRS, 5.7MG/24HRS, 7.6MG/24HRS
38278, 38476, 38589, 38609, 38618, 38619	BREXPIPRAZOLE 0.25 MG
39579, 39582, 39583, 39584	CARIPRAZINE 1.5MG, 3MG, 4.5MG, 6MG
18142, 21785, 98791, 28873, 28874, 31672, 18141, 21784, 18143, 14336	CLOZAPINE 100 MG, 12.5 MG, 150 MG, 200 MG, 25 MG, 50 MG, 50 MG/ML
47492	LUMATEPERONE TOSYLATE 42MG
28025, 28030, 28033, 28034, 28026, 28027, 28028, 28029	ILOPERIDONE 1 MG, 10 MG, 12 MG, 1-2-4-6MG, 2 MG, 4 MG, 6 MG, 8 MG
33147, 31226, 29366, 35192, 29367	LURASIDONE HCL 120MG, 20MG, 40MG, 60MG, 80MG
15082, 17407, 92008, 15085, 34022, 15084, 15086, 34023, 15083, 92007, 15081	OLANZAPINE 10 MG, 15 MG, 2.5 MG, 20 MG, 5 MG, 7.5 MG
27855, 27849, 27848	OLANZAPINE PAMOATE 210 MG, 300 MG, 405 MG
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG
27685, 97769, 97770, 97771	PALIPERIDONE 1.5 MG, 3 MG, 6 MG, 9 MG
27416, 27417, 27418, 38697, 27414, 38698, 38699, 27415, 38702	PALIPERIDONE PALMITATE 117MG/0.75, 156 MG/ML, 234MG/1.5, 273MG/.875, 39MG/0.25, 410/1.315, 546MG/1.75, 78MG/0.5ML, 819/2.625
67662, 16193, 67663, 98522, 67661, 67665, 98523, 26411, 98524, 26409, 98994	QUETIAPINE FUMARATE 100 MG, 150 MG, 200 MG, 25 MG, 300 MG, 400 MG, 50 MG
24448, 92872, 19541, 92892, 16136, 19178, 16135, 35049, 16137, 19179, 35051, 16138, 25024, 35052, 16139, 25025, 45127, 45128	RISPERIDONE 0.25 MG, 0.5 MG, 1 MG, 1 MG/ML, 2 MG, 2 MG/2 ML, 3 MG, 3 MG/3 ML, 4 MG, ER 90MG SYRINGE KIT, ER 120MG SYRINGE KIT
98414, 20217, 20218, 20219	RISPERIDONE MICROSPHERES 12.5MG/2ML, 25 MG/2 ML, 37.5MG/2ML, 50 MG/2 ML
13331, 13332, 13333, 13334	ZIPRASIDONE HCL 20 MG, 40 MG, 60 MG, 80 MG
17037	ZIPRASIDONE MESYLATE FNL 20MG/1

APPENDIX E

Edit 58660 - Concomitant use of two or more antidepressants(SSRIs).

GCN	Drug Description
16345, 16344, 16342, 34671, 16343	CITALOPRAM HYDROBROMIDE 10 MG, 10 MG/5 ML, 20 MG, 20 MG/10ML, 40 MG
17851, 17987, 18975, 19035	ESCITALOPRAM OXALATE 10 MG, 20 MG, 5 MG, 5 MG/5 ML
16353, 16356, 16354, 16359, 16357, 16355, 30817, 12929	FLUOXETINE HCL 10 MG, 20 MG, 20 MG/5 ML, 40 MG, 60 MG, 90 MG
16349, 99481, 99482, 16347, 16348	FLUVOXAMINE MALEATE 100MG, 150MG, 25MG, 50MG
20870, 20872, 98648, 20868, 20869	OLANZAPINE/FLUOXETINE HCL 12MG-25MG, 12MG-50MG, 3 MG-25 MG, 6MG-25MG, 6MG-50MG
16364, 16369, 17078, 16366, 17077, 16367, 17079, 16368	PAROXETINE HCL 10 MG, 10 MG/5 ML, 12.5 MG, 20 MG, 25 MG, 30 MG, 37.5 MG, 40 MG
20854, 20855, 20856, 20857	PAROXETINE MESYLATE 10 MG, 20 MG, 30 MG, 40 MG
16375, 16376, 16373, 16374	SERTRALINE HCL 100 MG, 20 MG/ML, 25 MG, 50 MG
29916, 31956, 29917, 29918	VILAZODONE HYDROCHLORIDE 10 MG, 10-20-40MG, 20 MG, 40 MG

APPENDIX F

Edit 58670 - Concomitant use of two or more antidepressants (SNRIs).

GCN	Drug Description
34482, 35584, 34470, 35582	DESVENLAFAXINE 100 MG, 50 MG
36273, 36272	DESVENLAFAXINE FUMARATE 100 MG, 50 MG
99452, 38222, 99451	DESVENLAFAXINE SUCCINATE 100 MG, 25 MG, 50 MG
23161, 23162, 38728, 23164	DULOXETINE HCL 20 MG, 30 MG, 40 MG, 60 MG
35334, 35327, 35335, 35328, 35329	LEVOMILNACIPRAN HYDROCHLORIDE 120 MG, 20 MG, 20-40MG, 40 MG, 80 MG
22022, 21979, 22025, 22008, 22019	MILNACIPRAN HCL 100 MG, 12.5 MG, 12.5-25-50, 25 MG, 50 MG
16815, 14353, 16818, 14354, 16811, 14349, 16812, 16816, 16813, 14352, 16814, 16817	VENLAFAXINE HCL 100 MG, 150 MG, 225 MG, 25 MG, 37.5 MG, 50 MG, 75 MG

APPENDIX G

Edit 58680 - Concomitant use of two or more anxiolytics.

GCN	Drug Description
14260, 24368, 14261, 17423, 24369, 14262, 17424, 24373, 14264, 14263, 17425, 24374, 19681	ALPRAZOLAM 0.25 MG, 0.5 MG, 1 MG, 1 MG/ML, 2 MG, 3 MG
14031, 14032, 14033	CHLORDIAZEPOXIDE HCL 10 MG, 25 MG, 5 MG
14090, 14092, 14093	CLORAZEPATE DIPOTASSIUM 15 MG, 3.75 MG, 7.5 MG
14220, 14221, 14222, 31551, 45560, 14200, 14210, 45500	DIAZEPAM 10 MG, 2 MG, 5 MG, 5 MG/5 ML, 5 MG/ML
14140, 14150, 19601, 14141, 14151	LORAZEPAM 2 MG/ML, 4 MG/ML
13801, 13802	MEPROBAMATE 200 MG, 400 MG
14230, 14231, 14232	OXAZEPAM 10 MG, 15 MG, 30 MG

APPENDIX H

Edit 7610 - Quantities in excess of the dosages recommended by the Food and Drug Administration (FDA) for the behavioral health medications (does not include antidepressants, atypical antipsychotics, stimulants and ADD/ADHD medications).

GCN	Drug Description	Quantity	Days Supply
17423, 17424, 17425, 19681	ALPRAZOLAM 0.5 MG, 1 MG, 2 MG, 3 MG	60	30
24368, 24369, 24373, 14263, 24374	ALPRAZOLAM 0.25 MG, 0.5 MG, 1 MG, 2 MG	90	30
14260, 14261, 14262, 14264	ALPRAZOLAM 0.25 MG, 0.5 MG, 1 MG, 1 MG/ML	180	30
16683, 16684	AMITRIP HCL/CHLORDIAZEPOXIDE 12.5MG-5MG, 25 MG-10MG	180	30
98590, 36082, 98592, 98591	ARMODAFINIL 150 MG, 200 MG, 250 MG, 50 MG	30	30
64672	BUPRENORPHINE HCL 2MG	90	30
64673	BUPRENORPHINE HCL 8 MG	60	30
44187	BUPRENORPHINE XR 100MG/0.5ML	0.5ML	30
44186	BUPRENORPHINE XR 300MG/1.5ML	1.5ML	30
33744, 37823	BUPRENORPHINE HCL/NALOXONE HCL 12 MG-3 MG, 8.6-2.1 MG	30	30
33741	BUPRENORPHINE HCL/NALOXONE 4MG-1MG	30	30
34905, 18974, 28959	BUPRENORPHINE HCL/NALOXONE HCL 5.7-1.4 MG, 8 MG-2 MG	60	30
39394	BUPRENORPHINE HCL/NALOXONE HCL 2.9-0.71MG	30	30
37824	BUPRENORPHINE HCL/NALOXONE 11.4-2.9MG	30	30
36677, 36678	BUPRENORPHINE / NALOXONE 2.1-0.3MG, 4.2-0.7MG	60	30
36679	BUPRENORPHINE / NALOXONE 6.3-1MG	30	30
34904, 18973, 28958	BUPRENORPHINE HCL/NALOXONE HCL 1.4-0.36MG, 2 MG-0.5MG	90	30
42843	BUPRENORPHINE / NALOXONE 0.7-0.18 MG	30	30
14031, 14032, 14033	CHLORDIAZEPOXIDE HCL 10 MG, 25 MG, 5 MG	360	30
19467, 19468, 17470, 19469, 17471, 19470	CLONAZEPAM 0.125 MG, 0.25 MG, 0.5 MG, 1 MG	180	30
17472, 19472	CLONAZEPAM 2 MG	300	30
14090, 14092, 14093	CLORAZEPATE DIPOTASSIUM 15 MG, 3.75 MG, 7.5 MG	180	30
29290	DEXTROMETHORPHAN HBR/QUINIDINE 20 MG-10MG	60	30
14220	DIAZEPAM 10 MG	120	30
14222	DIAZEPAM 5 MG	180	30
14221, 45500	DIAZEPAM 2 MG, 5 MG/ML	240	30
31551, 45560	DIAZEPAM 5 MG/5 ML	1200	30

GCN	Drug Description	Quantity	Days Supply
14160, 14161	LORAZEPAM 0.5 MG, 1 MG	90	30
14162, 19601	LORAZEPAM 2 MG, 2 MG/ML	150	30
26101, 26102	MODAFINIL 100 MG, 200 MG	30	30
27095	NALTREXONE MICROSPHERES 380MG	1	28
14231, 14232	OXAZEPAM 15 MG, 30 MG	120	30
14230	OXAZEPAM 10 MG	240	30
18104	SODIUM OXYBATE 500 MG/ML	675	30

Criteria Change Log	
May 1, 2017	Criteria effective date
July 20, 2017 – July 5, 2017	Repost for Appendix Updates Appendix A – added GCN, drug description, quantity days supply for: aripiprazole lauroxil, asenapine 2.5mg, brexpiprazole, cariprazine, olanzapine, paliperidone palmitate; lurasidone 60mg quantity changed to 30, risperidone 4mg quantity changed to 30 Appendix B - GCN 16385 duplication deleted Appendix D - added GCN, drug description, quantity, days supply for: aripiprazole lauroxil, brexpiprazole, cariprazine
July 6, 2017	No public comments to policy Appendix updates
July 11, 2017	Appendix updates incorporated in policy
December 4, 2018	Appendix C added GCNs for methylphenidate XR
December 4, 2018	Appendix H changed GCN 64673 to quantity 60
December 4, 2018	Appendix H added GCNs 44186, 44187
December 4, 2018	Appendix H changed GCN 33741 to quantity 30
December 4, 2018	Appendix H added GCNs 39394, 37824, 36677,36678, 36679, 42843
December 4, 2018	Changed edit numbers 5110 to 7110; 5125 to 7125; 5140 to 7140; 5410 to 58650; 5420 to 58660; 5421 to 58670; 5440 to 58680; 5610 to 7610
July 1, 2019	Add GCN 45127, 45128, 44941 to Appendix A and D
July 1, 2019	Add GCN 44437, 44438, 44439, 44441, 44442, 44443 to Appendix A and D
July 1, 2019	Add GCN 46077, 46078 and 46079 to Appendix H
December 16, 2019	Change edit 58670 to less than 18 years of age
December 16, 2019	Add GCN 16364, 16366, 16367, 16368, 17078, 17079 to Appendix B
December 16, 2019	Remove GCN 46077, 46078, 46079 from Appendix H
April 1, 2021	Add GCN 47492 to Appendix A and Appendix D
April 1, 2021	Add GCNs 47229, 47232, 47233 to Appendix A and Appendix D
April 1, 2021	Add edit descriptions to Appendix A through Appendix H

WellCare of North Carolina
Prior Authorization Criteria
Crinone 8% Gel (progesterone)

Effective Date: 11/01/14
Amended Date: 04/13/21

Therapeutic Class Code: G2A
Therapeutic Class Description: Progestational Agents

Medication
Crinone 8% Gel (progesterone)

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) shall not cover the NC Division of Medical Assistance Outpatient Pharmacy Prior Approval Criteria for Crinone 8% Gel (progesterone).

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DHB clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria:

- Documented ultrasound of transvaginal cervical length (TVCL) ≤ 25mm between weeks 17 and 24 of gestation OR
- Diagnosis of secondary amenorrhea in patients who have failed Crinone 4% gel
- Crinone 8% is not being used for infertility

Procedures:

- Approve for 2 boxes (15 single use applicators per box) per 30 days
- Approve until the end of pregnancy; For secondary amenorrhea: approve for 12 months

References

1. Romero R, Niolaides K, Conde-Agudelo A, et al. Vaginal progesterone in women with an asymptomatic sonographic short cervix in the mid trimester decreases preterm delivery and neonatal morbidity: a systematic review and metaanalysis of individual patient data. Am J Obstet Gynecol 2012;206:124.e1-19

2. Campbell S. Universal Cervical length screening and vaginal progesterone prevents early preterm births, reduces neonatal morbidity and is cost saving: doing nothing is no longer an option. Ultrasound Obstet Gynecol. 38 (1), 1-9 (2011)

3. Fonseca, EB. Progesterone and the risk of preterm birth among women with a short cervix. N Engl J Med 2007 Aug, 2:357(5): 462-9

4. DeFranco, E.A., et al. Vaginal progesterone is associated with a decrease in risk for early preterm birth and improved neonatal outcome in women with a short cervix: a secondary analysis from a randomized, double-blind, placebo-controlled trial. Ultrasound Obstet Gynecol 2007; 30: 697–705

5. O'Brien, J.M, et al. Effect of progesterone on cervical shortening in women at risk for preterm birth: secondary analysis from a multinational, randomized, double-blind, placebo-controlled trial. Ultrasound Obstet Gynecol 2009; 34: 653-659

6. Crinone [package insert]. Irvine, CA; Allergan. June 2017.

Criteria Change Log

11/01/2014	Criteria effective date
04/13/2021	Removed GSNs Added secondary amenorrhea to document for coverage

WellCare of North Carolina
Prior Authorization Criteria **Effective Date: April 14, 2021**
Evrysdi

Therapeutic Class Code: Z1T
Therapeutic Class Description: GENETIC D/O TX - SMN PROTEIN DEFICIENCY TREATMENT

Medication
Evrysdi

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.

b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to
correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.

IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage of Evrysdi:

- Patient ≥ 2 months of age;

  AND

- Patient has a diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA);

  AND

- Patient must have SMA phenotype 1, 2 or 3;

  AND

- Must not be used concomitantly with nusinersen (Spinraza) or onasemnogene abeparvovec-xioi (Zolgensma);

  AND

- Prescribed by or in consultation with a neurologist

  AND

- Initial approval shall be for up to 12 months.

Criteria for Continuation of Coverage of Evrysdi:

- Patient continues to meet the above initial criteria;

  AND

- Absence of unacceptable toxicity or treatment related adverse event from the drug;

  AND

- Patient has clinically meaningful response to treatment as demonstrated by at least 1 of the following:

- Stability or improvement in net motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), Upper Limb Module (ULM), Motor Function Measure-32 (MFM-32), Revised Upper Limb Module (RULM) etc.
- Stability or improvement in respiratory function tests [e.g., forced vital capacity (FVC), etc.
- Reduction in exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
- Stable or increased patient weight (for patients without a gastrostomy tube)
- Slowed rate of decline in the aforementioned measures

- Continuation approvals shall be for up to 12 months

References

1. Evrysdi [package insert]. San Franciso, CA; Genentech; August 2020.

Criteria Change Log

04/14/2021	Criteria effective date

WellCare of North Carolina
Prior Authorization Criteria
Growth Hormones

Effective Date: March 4, 2002
Revised Date: April 14, 2021

Therapeutic Class Code: P1A, P7A
Therapeutic Class Description: Growth Hormones

Medications
Genotropin and Genotropin Miniquick
Humatrope
Norditropin
Nutropin AQ and Nuspin
Omnitrope
Saizen
Zomacton
Zorbtive
Increlex

Use of Serostim for AIDS wasting syndrome is exempted from this policy and does not require prior approval.

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health

problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.
Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional healthproblems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

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https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy**

prior approval clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria (excludes Zorbtive and Increlex)

A. Adults with growth hormone deficiency

Coverage is provided in the presence of all the following:

1. Biochemical diagnosis of somatotropin deficiency by means of a negative response to a standard growth hormone (GH) stimulation test
2. This deficiency, either alone or with multiple hormone deficiencies, is a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
3. Adult beneficiaries who were diagnosed with GH deficiency in childhood must have a low level of insulin-like growth factor–1 (IGF-1) after having been off GH therapy for at least 1 month

Continuation of Therapy inadults

Adult beneficiaries with genetic causes of GH deficiency/hypopituitarism and multiple pituitary hormone deficiencies are exempt from criteria requirements.

B. Children with growth hormone deficiency

Coverage is provided in the presence of all the following:

1. GH dysfunction or lack of adequate endogenous GH documented by any of two provocative tests of less than 10mg/ml
2. Beneficiary's height must be below the third percentile for their age and gender related height
3. Epiphysis confirmed as open in beneficiaries greater than 9 years of age

C. Beneficiaries with the following conditions (no requirement for growth hormone stimulation testing):

1. Children with craniopharyngiomas
2. Children with multiple pituitary hormone deficiencies (panhypopituitarism) who have abnormal height velocity (height velocity <25th percentile for bone age) and low serum levels of IGF-1 and insulin-like growth factor binding protein–3 (IGFBP-3)
3. Children with abnormal height velocity (height velocity <25th percentile for bone age), low IGF-1/IGFBP-3 levels, and anatomic (MRI) evidence of hypopituitarism (ectopic posterior pituitary bright spot, small or hypoplastic pituitary gland or stalk, or empty sella)
4. Adequately nourished infants or children who have hypoglycemia and low GH

response to hypoglycemia and who show other signs of hypopituitarism

5. Children who have received cranial irradiation with a decreased height velocity (height
velocity <25th percentile for bone age) who show other evidence of hypopituitarism (one or more additional pituitary hormone deficiencies)

D. Coverage for a trial of GH therapy is provided for children with otherwise unexplained short stature who may pass GH stimulation tests, but who meet all of the following criteria

1. Height >2.25 standard deviations below mean for age
2. Height velocity <25th percentile for bone age
3. Bone age >2 standard deviations below mean for age
4. Low serum IGF-1/IGFBP-3

E. Coverage is provided in the absence of documented growth hormone deficiency, stimulation tests, or IGF-1 levels in the following situations

1. Beneficiaries with Turner's syndrome
2. Children with height less than 3rd percentile for chronologic age with chronic renal insufficiency
3. Beneficiaries with Prader-Willi syndrome
4. Children who were born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) in whom the birth weight and/or length were more than 2 standard deviations below the mean for gestational age, and who fail to show catch-up growth by age 2 (defined as a height velocity below 1 standard deviation score, adjusted for age)

Increlex

Therapy with Increlex (IGF-I) must be reserved for children with growth failure that will not respond to GH therapy: those with GH resistance caused by a mutation in the GH receptor or post-GH receptor signaling pathway, or IGF-I gene defects, or individuals with GH gene deletions who have developed neutralizing antibodies to GH. In addition, children with severe short stature may be considered for Increlex therapy if they have failed a trial of GH therapy. Children must have a height less than 3 SDs below the mean, an IGF-I level less than 3 SDs below the mean, and normal or elevated GHlevels.

Zorbtive

Therapy with Zorbtive must be reserved for beneficiaries with short bowel syndrome.

Continuation of Therapy inChildren:

Coverage is provided in the presence of all of the following criteria:
1. A growth response of greater than 4.5 cm/year (pre-pubertal growth phase) or greater than 2.5 cm/year (post-pubertal growth phase) must occur for continuation of coverage.
2. Minimum yearly IGF-I and/or IGFBP-3 monitoring must be performed, and results must be within age-appropriate ranges.

(Children with genetic causes of GH deficiency/hypopituitarism and multiple pituitary hormone deficiencies are exempt from criteria requirements.)

Procedures:

1. The P&T recommends that a pharmacist handle all prior authorization requests for this therapeutic class.
2. The request must come from the physician's office.
3. Approval length up to one year.

References

1. Wilson TA et al. Update of guidelines for the use of growth hormone in children. *Journal of Pediatrics.* 2003. 143; 415-21
2. Maison P, Griffin S, Nicoue-Beglah M, Haddad N, Balkau B, Chanson P. Impact of growth hormone (GH) treatment of cardiovascular risk factors in GH-deficient adults: a meta-analysis of blinded, placebo controlled trials. *The Journal of Clinical Endocrinology and Metabolism.* 2004. 89(5): 2192-2199
3. Liu H, Bravata DM, Olkin I, Nayak S, Roberts B, Garber AM, Hoffman AR. Systematic review: the safety and efficacy of growth hormone in the healthy elderly. *Ann Intern Med.* 2007. 146(2):104-15
4. Zhou Y, Xiao-Ting W, Yang G, Zhunag W, Wei M. Clinical evidence of growth hormone, glutamine and a modified diet for short bowel syndrome: meta-analysis of clinical trials. *Asia Pac J Clin Nutr.* 2005. 14(1):98-102.
5. Davies PSW. Growth hormone therapy in Prader-Willi Syndrome. *International J of Obesity.* 2001. 25:2-7.
6. Rapaport R, Tuvemo T. Growth and growth hormone in children born small for gestational age. *Acta Paediatrica.* 2005. 94:1348-1355.
7. Serono Laboratories, Inc. Serostim package insert. Randolph, MA: 2001 Jun.
8. Serono Laboratories, Inc. Saizen package insert. Randolph, MA: 2000 Sep.
9. Genentech, Inc. Protropin package insert. San Francisco, CA: 1999 Jan.
10. Genentech, Inc. Nutropin package insert. San Francisco, CA: 2000 Apr.
11. Eli Lilly and Company. Humatrope package insert. Indianapolis, IN: 2001 Feb.
12. Pharmacia & Upjohn Company. Genotropin package insert. Kalamazoo, MI: 2001Jul.
13. Ferring Pharmaceuticals, Inc. Zomacton package insert. Parsippany, NJ: 2015 Mar.

Criteria Change Log

03/04/2002	Criteria effective date
05/04/2009	Added coverage for children with craniopharyngiomas, panhypopituitarism, and unexplained short stature. Added continuation criteria
06/15/2012	Combined NC Medicaid and NC Health Choice criteria into one (no changes to criteria)
11/01/2014	Added new GCN for Nutropin
11/01/2015	Added criteria for Zomacton
02/26/2019	Removed old GCN's for Nutropin. Update name to Nutropin Nuspin
04/13/2021	Remove GCN's, Remove Norditropin Nordiflex, Remove Tev-Tropin

WellCare of North Carolina
Prior Authorization Criteria
Juxtapid (lomitapide)

Effective Date: August 15, 2014
Amended Date: April 14, 2021

Therapeutic Class Code: M4Q
Therapeutic Class Description: Antihyperlipidimic-MTP Inhibitor and Antihyperlipidemic – Apolipoprotein B-100 Synthesis Inhibitor

Medication
Juxtapid

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to

correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Coverage:

- Recipient has been diagnosed with homozygous familial hypercholesterolemia (HoFH).
  and
- Enrolled in Juxtapid REMS program (for Juxtapid)
  and
- At least 18 years old or older.
  and
- Beneficiary is receiving concurrent lipid lowering therapy or is unable to use concurrent lipid lowering therapy
  and
- Obtain a negative pregnancy test in females of reproductive potential.
  and
- Measure ALT, AST, alkaline phosphatase, and total bilirubin before initiating treatment
  and
- During the first year, measure liver-related tests (ALT and AST, at a minimum) prior to each increase in dose or monthly, whichever occurs first. After the first year, do these tests at least every 3 months and before any increase in dose.

Procedures:
Approval may be for up to 1 year for up to 60mg once a day

References

1. Prescribing Information-Juxtapid® (lomitapide) Aegerion Pharmaceuticals, Inc., Cambridge, Massachusetts 02142. December 2012.

Criteria Change Log

08/15/2014	Criteria effective date (Juxtapid only)
01/20/2016	Added criteria for Kynamro
04/14/2021	Remove GCNs, Remove Kynamro (off market)

WellCare of North Carolina Prior Authorization Criteria Treatment for Movement Disorders

Effective Date: February 8, 2018
Amended Date: April 13, 2021

Therapeutic Class Code: H6L
Therapeutic Class Description: Drugs to Treat Movement Disorders

Medication
Ingrezza
Austedo
Xenazine
tetrabenazine

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years

of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

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EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

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correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

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1. Ingrezza

a. Tardive Dyskinesia

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of moderate to severe Tardive Dyskinesia.
- Beneficiary is age 18 or older.
- Provider has completed baseline evaluation of the condition using either: Abnormal Involuntary Movement Scale (AIMS) or Extrapyramidal Symptom Rating Scale (ESRI) and has submitted score
- Beneficiary has had a previous trial of an alternative method to manage the condition.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.

  Reauthorization shall be for up to 12 months.

2. Austedo

a. Tardive Dyskinesia

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of moderate to severe TardiveDyskinesia. Beneficiary is age 18 or
- older.

- Provider has completed baseline evaluation of the condition using either: Abnormal Involuntary Movement Scale (AIMS) or Extrapyramidal Symptom Rating Scale (ESRI) and has submitted score
- Beneficiary has had a previous trial of an alternative method to manage the condition.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

b. Huntington's Disease

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of Huntington's Disease and is experiencing signs and symptoms of chorea
- Beneficiary is age 18 or older.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable.
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.
-

3. Xenazine and tetrabenazine

a. Huntington's Disease

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of Huntington's Disease and is experiencing signs and symptoms of chorea
  Beneficiary is age 18 or older.
-
  Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
  Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or

reserpine.

- Initial approval shall be for up to 6 months.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

References

1. Prescriber Information—Ingrezza®. Neurocrine Biosciences, Inc., San Diego, CA. April 2017.
2. Prescriber Information—Xenazine®. Lundbeck, Deerfield, IL. revised September 2017.
3. Prescriber Information—Austedo®. Teva Pharmaceuticals, USA, Inc.,North Wales, PA. revised August 2017. Revised July 2019.

WellCare of North Carolina
Prior Authorization Criteria
Treatment for Movement Disorders

Effective Date: February 8, 2018
Amended Date: April 13, 2021

Criteria Change Log	
02/08/2018	Criteria effective date
11/21/2018	Added criteria for Austedo, Xenazine, and tetrabenazine
04/13/2021	Removed requirement for documentation of baseline assessment to be submitted for tardive dyskinesia indication. Replaced with submission of score.
04/13/2021	Remove Step through Austedo added for Ingrezza and Remove Step through tetrabenazine added for diagnosis of HD for Austedo

WellCare of North Carolina Prior Authoriation Criteria Sedative Hypnotics

Effective Date: May 1, 2006
Amended Date: April 13, 2021

Therapeutic Class Code: H2E, H8B
Therapeutic Class Description: Sedative Hypnotics—Non-Barbiturate, Hypnotics, Melatonin MT1/MT2 Receptor Agonists

Medication
Ambien, Ambien CR, zolpidem, zolpidem ER, Zolpimist, Intermezzo, zolpidem SL,Edluar
zaleplon
estazolam
flurazepam
Halcion, triazolam
Doral
Restoril, temazepam
Lunesta, eszopiclone
Rozerem, ramelteon
Silenor, doxepin
Belsomra
Dayvigo

Eligible Beneficiaries
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b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to
correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria

Exceeding Quantity Limit of 15 units per Calendar Month (oral tablets/capsules/SL tablets) or Zolpimist (oral spray) –one canister per 60days

a. Beneficiary must have a diagnosis of chronic primary insomnia lasting one month or longer. Beneficiary must have received information on good sleep hygiene and have a documented trial (at least 3 weeks) of non-pharmacological therapies (e.g. stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy). Length of therapy may be approved for up to six months at a time.
OR
b. Beneficiary must have a diagnosis of chronic secondary or co-morbid insomnia lasting one month

or longer and has been evaluated for and is being actively treated for one of the following conditions:

1. an underlying psychiatric illness associated with insomnia
2. an underlying medical illness associated with insomnia (for example, chronic pain associated with cancer, inflammatory arthritis)
3. a sleep disorder such as restless legs syndrome, sleep-related breathing disorder, sleep-related movement disorder, or circadian rhythm disorder. Length of therapy may be approved for up to six months at a time.

OR

c. Beneficiary is being discontinued from a sedative hypnotic and tapering is required to prevent symptoms of withdrawal. Length of therapy may be approved for up to three months at a time.

OR

d. Beneficiary is being actively assessed for a diagnosis of chronic primary or secondary/co-morbid insomnia. Beneficiary must have received information on good sleep hygiene and have a documented trial (at least 3 weeks) of non-pharmacological therapies (e.g. stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy). Length of therapy may be approved for six months one time only. Additional information may be requested to substantiate this status.

Procedures

a. Changes in strength will not require additional prior authorization.
b. Prior authorization request forms will be accepted when submitted by mail or facsimile telecommunication methods only.
c. Beneficiaries residing in skilled nursing facilities, intermediate care facilities, and intermediate care facilities for individuals with mental retardation are exempt from the prior authorization requirement for sedative hypnotics.

FDA Recommendations 2013

To reduce risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem and warns about risks of next day impairment (Ambien, Ambien CR, Edluar, and Zolpimist)"

a. **For certain immediate-release zolpidem products (Ambien, Edluar, and Zolpimist) the recommended initial dose for women should be lowered from 10 mg to 5 mg, immediately before** bedtime. Lower dose of 5 mg for men should be considered as well. For both men and women, the 5 mg dose could be increased to 10 mg if needed, but the higher dose is more likely to impair next-morning driving and other activities that require full alertness.

b. **For extended-release zolpidem (Ambien CR) the recommended initial dose for women should be lowered from 12.5 mg to 6.25 mg, immediately before bedtime. Lower dose of 6.25 mg in men should be considered in men as well**. For both men and women, the 6.25 mg dose can be increased to 12.5 mg if needed, but the higher dose is more likely to impair next-morning driving and other activities that require full alertness.

c. For zolpidem and other insomnia drugs, prescribe the lowest dose that treats the patient's symptoms.

d. **The FDA urges health care professionals to caution all patients (men and women) who use these products about the risks of next-morning impairment for activities that require complete mental alertness, including driving**. Inform patients that impairment from sleep drugs can be present despite feeling fully awake.

e. **Patients who take the sleep medication zolpidem extended-release (Ambien CR)—either 6.25 mg or 12.5 mg—should not drive or engage in other activities that require complete mental alertness the day after taking the drug** because zolpidem levels can remain high enough the next day to impair these activities. This new recommendation has been added to the *Warnings and Precautions* section of the physician label and to the patient Medication Guide for zolpidem extended-release (AmbienCR).

Glossary[18]

a. **Chronic Insomnia:** Insomnia may be defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance may consist of one or more of three features: (1) difficulty in initiating sleep; (2) difficulty in maintaining sleep; or (3) waking up too early. A fourth characteristic, non-restorative or poor-quality sleep, has frequently been included in the definition, although there is controversy as to whether individuals with this complaint share similar pathophysiologic mechanisms with the others. Chronic insomnia has been defined by the recent NIH consensus panel as 30 days or more of the symptoms described above.

b. **Primary Chronic Insomnia:** "Primary insomnia" is the term used when no coexisting disorder has been identified.

c. **Secondary or Co-Morbid Insomnia**: Most cases of insomnia are co-morbid with other conditions. Historically, this has been termed "secondary insomnia." However, the limited understanding of mechanistic pathways in chronic insomnia precludes drawing firm conclusions about the nature of these associations or the direction of causality.

References

1. Sanofi-Synthelabo Inc. Ambien package insert. New York: March 2004.
2. Sanofi-Synthelabo Inc. Ambien CR package insert. New York: Sept. 2005.
3. ICN Pharmaceuticals, Inc. Dalmane package insert. Costa Mesa, CA: Sept. 2001.
4. Medpointe Healthcare, Inc. Doral package insert. Somerset, NJ: 2001.
5. Pharmacia Corp. Halcion package insert. Kalamazoo, MI: Jan. 2003.
6. Abbott Laboratories. ProSom package insert. Chicago, Il, Jan. 2004.
7. Mallinckrodt, Inc. Restoril package insert. St. Louis, MO.
8. Wyeth Pharmaceuticals. Sonata package insert. Philadelphia, PA: Dec. 2004.
9. *Insomnia: Assessment and Management in Primary Care.* NIH Publication No. 98-4088. Sept. 1998.
10. *Manifestations and Management of Chronic Insomnia in Adults*. NIH State-of-the-Science Conference Statement. June 15, 2005.
11. *Drug Class Review on Newer Sedative-Hypnotics, Final Report.* Portland, OR: Oregon Evidence-based Practice Center, Oregon Health and Science University, Dec. 2005.
12. Buscemi N, Vandermeer B, Friesen C, Bialy L, Tubman M, Ospina M, Klassen TP, Witmans M. Manifestations and Management of Chronic Insomnia in Adults. Evidence Report/Technology
13. Assessment No. 125. (Prepared by the University of Alberta Evidence-based Practice Center,

under Contract No. C400000021.) AHRQ Publication No. 05-E021-2. Rockville, MD: Agency for Healthcare Research and Quality. June 2005.

14. American Academy of Family Physicians. Information from your family doctor: Sleep changes in older adults. *Am Fam Physician* 2005 Oct 1;72(7):1315-6.
15. American Academy of Family Physicians. Information from your family doctor. Insomnia: how to get a good night's sleep. *Am Fam Physician.* 2005 Oct 1;72(7):1309-10.
16. Patient handout. Sleep talk with your doctor. *Geriatrics*. 2004 Jan;59(1):33-4.
17. Parmet S, Lynm C, Glass RM. JAMA patient page. Insomnia. *JAMA*. 2003 May 21;289(19):2602.
18. Page for patients. Sleep. Prev Med. *Prev Med.* 2002 Jun;34(6):579-80.
19. National Institutes of Health State of the Science Conference statement on Manifestations and Management of Chronic Insomnia in Adults, June 13-15, 2005. Sleep. 2005 Sep 1;28(9):1049-57.
20. ECR Pharmaceuticals. Zolpimist package insert. Richmond, Virginia: 2010
21. Belsomra Package Insert. Merck, Sharp, and Dome., 2014.

Criteria Change Log

05/01/2006	Criteria effective date
05/15/2009	Coverage for up to 15 units per drug class without PA
12/13/2011	Add coverage for Zolpimist and dosing limits
09/13/2012	Added FDA guidance for zolpidem dosing
08/01/2014	Update quantity limits
08/15/2014	Removed brand name Prosom and Dalmane
06/10/2015	Add coverage for Belsomra
07/09/2020	Remove GSNs, add generic ramelteon, generic eszopiclone, generic zolpidem SL, Remove brand name Sonata
04/13/2021	Add generic for Doxepin
04/13/2021	Add Dayvigo

WellCare of North Carolina
Prior Authorization Criteria
Systems (CGM) and Related Supplies

Effective Date: July 1, 2020
Amended Date: April 8, 2021

Therapeutic Class Code: Y9A
Therapeutic Class Description: Continuous Glucose Monitoring Systems and Supplies

Medications
Dexcom Continuous Glucose Monitoring System and Supplies- G5 mobile and G6 Therapeutic Products
FreeStyle Libre and FreeStyle Libre 2 Continuous Glucose Monitoring System and Supplies- Therapeutic Products

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Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

A typical Continuous Glucose Monitoring (CGM) system continuously measures glucose values in the interstitial fluid and consists of a glucose sensor, transmitter and receiver. Only CGM systems classified by the FDA as therapeutic will be considered for coverage under Outpatient Pharmacy Criteria. Coverage criteria for non-therapeutic CGM systems can be found at NC Medicaid Clinical Coverage Policy 5A-3 (Durable Medical Equipment benefit (DME)).

Therapeutic CGMs are approved by the FDA for use as non-adjunctive devices to replace information obtained from standard BGMs in making diabetes treatment decisions.

Criteria:

- Initial prior authorization: Beneficiary must meet criteria one through six (1-6) or one and seven (1 and 7).
  1. the beneficiary has a diagnosis of insulin-dependent diabetes; and,
  2. the beneficiary has been using a standard BGM (blood glucose monitor) and testing four (4) or more times daily or using a non-therapeutic CGM; and,
  3. the beneficiary requires two (2) or more insulin injections daily; and,
  4. the beneficiary's insulin treatment regimen requires frequent adjustment based on standard BGM or non-therapeutic CGM testing; and,
  5. the beneficiary or caregiver(s) is willing and able to use the therapeutic CGM system as prescribed; and,
  6. the beneficiary has had a face-to-face encounter with the treating practitioner to evaluate the beneficiary's glycemic control and determine that criteria one through five (1-5) above have been met, within six months of the initial authorization request; or,

7. the beneficiary uses an external insulin pump.

Coverage for Dexcom G5 and G6 for ages 2 and older
Coverage for FreeStyle Libre for ages 18 and older
Coverage for FreeStyle Libre 2 for ages 4 and older

The initial prior authorization period must not exceed six months.

- **First reauthorization:** After the initial authorization period, the first reauthorization request must include documentation that:
  1. the beneficiary has been using the CGM system as prescribed; and,
  2. the beneficiary has been able to improve glycemic control; or,
  3. the beneficiary continues to use an external insulin pump.

Reauthorization must not exceed 12 months.

Subsequent reauthorizations: After the initial authorization and first reauthorization periods, each subsequent reauthorization request for a therapeutic CGM and related supplies must include documentation that:

1. the beneficiary has had a face-to-face encounter with the ordering practitioner to evaluate the efficacy of the CGM system no more than three (3) months prior to submission of the reauthorization request; and,
2. the beneficiary has been using the CGM system as prescribed; and,
3. the beneficiary has been able to maintain or further improve glycemic control; or,
4. the beneficiary continues to use an external insulin pump.

Reauthorization must not exceed twelve (12) months.
Note: The beneficiary must meet the FDA age limits and other requirements for the specific device prescribed.

Note: Simultaneous coverage for more than one therapeutic CGM system is not permitted.

Coverage criteria for non-therapeutic continuous glucose monitoring systems can be found at https://medicaid.ncdhhs.gov/providers/programs-services/medical/durable-medical-equipment

References

1. Dexcom Provider Website: https://provider.dexcom.com/
2. FreeStyle Libre Provider Website: https://www.myfreestyle.com/provider/?source=www.freestylelibre.us
3. FreeStyle Libre 2 Provider Website:

   https://provider.myfreestyle.com/safety-information.html#indication-fsl2

Criteria Change Log

07/01/2020	Criteria effective date
04/08/2021	Added coverage for FreeStyle Libre 2 for ages 4 and older

WellCare of North Carolina
Prior Authorization Criteria
Triptans

Effective Date: July 20, 2009
Amended Date: April 13, 2021

Therapeutic Class Code: H3F
Therapeutic Class Description: Antimigraine Preparations

Medication
Amerge, naratriptan
almotriptan
Frova, frovatriptan
Imitrex, Migranow Kit, sumatriptan, Sumavel Dose Pro, Onzetra Xsail, Tosymra, Zembrace Symtouch
Maxalt/Maxalt-MLT, rizatriptan, rizatriptan ODT
Relpax, eletriptan
Treximet, sumatriptan/naproxen
Zomig/ Zomig ZMT, zolmitriptan, zolmitriptan ODT

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the

delivery of the needed service; and the
determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, orprocedure

a. that is unsafe, ineffective, orexperimental/investigational.

b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHCbeneficiaries.

Criteria

The following criteria must be met to exceed 12 units (doses) of a Triptan (oral tablets, nasal sprays, injections).

If different types of Triptans are required in a single month, the total maximum number of allowable units that can be obtained without prior approval remains the same. The same criteria must be fulfilled to obtain more than 12 units (doses) of combinedproducts:

1. Documentation in beneficiary chart of diagnostic criteria for migraine headache or

cluster headache.

AND

2. Greater than six moderate or severe headache days a month.

AND

3. Beneficiary must have tried and failed nonsteroidal anti-inflammatory (NSAIDS) within the last year or currently using NSAIDS, unless contraindicated.

AND

4. Beneficiary must concurrently be using migraine preventative medication(s) (i.e. Beta-Blockers, Tricyclic Antidepressants, Anticonvulsants) unless contraindicated, adverse effects occurred or no clinical benefit occurred after at least a 90 day trial at maximum tolerated dose.

AND

5. Beneficiary must not have history, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes; cardiovascular diseases; any type of angina pectoris, myocardial infarction(MI), or strokes; silent myocardial ischemia; transient ischemic attacks; ischemic bowel disease; uncontrolled hypertension; concurrent MAO-A inhibitor therapy (or within 2 weeks of discontinuing MAO-A inhibitor therapy); concurrent use of (or use within 24 hoursof) ergotamine-containing or ergot-type medication; concurrent use within 24 hours of another 5-HT1 agonist; or hemiplegic or basilar migraine.

AND

6. Prescribing clinician has reviewed recommendations below based on evidence based studies.

Recommendations from Evidence Based Studies

Recommendation 1: For most migraine sufferers, nonsteroidal anti-inflammatory drugs(NSAIDs) are first line therapy

Recommendation 2: In patients whose migraine headaches do not respond to NSAIDs, use migraine specific therapy (triptans, dihydroergotamines)

Recommendation 3: Select a non-oral route of administration for patients whose migraines present early with nausea or vomiting as a significant component of the symptom complex. Treat nausea and vomiting with an anti-emetic.

Recommendation 4: Migraine sufferers should be evaluated for use of preventive therapy.

Recommendation 5: Recommended first line agents for prevention of headaches are Beta Blockers, Tricyclic Antidepressants, and Anticonvulsants.

Recommendation 6: Educate migraine sufferers about the control of acute attacks and preventive therapy and engage them in the formulation of a management plan. Therapy should be re-evaluated on a regular basis.

Procedures

Length of therapy may be approved up to 12 months.

References

1. Snow V, Weiss K, Wall EM, Mottur-Pilson C. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. Ann Intern Med. 2002. 137:840-849

2. Silberstein SD. Practice parameter: evidence based guidelines for migraine headaches (an evidence based review): report of the quality standards subcommittee of the American Academy of Neuorology. Neurology 2000. 55:754-762

3. Treatment of primary headache: preventive treatment of migraine. Standards of care for headache diagnosis and treatment. 2004. National Guideline Clearinghouse. www.guideline.gov.

4. Drug Effectiveness Review Project. Oregon Health Sciences University. Triptan Final Report2005. viewed on 1-08 at www.ohsu.edu/drugeffectiveness/reports/

Criteria Change Log

07/20/2009	Criteria effective date
06/15/2012	Combined NC Medicaid and NC Health Choice criteria into one and add coverage for Sumavel
08/15/2014	Add coverage criteria for Alsuma
12/04/2014	Add GCN for Sumavel
09/22/2015	Add GCN for Zomig
04/13/2021	Remove GCNs, Remove Alsuma & Axert, Add frovatriptan, Migranow Kit, Onzetra Xsail, Tosymra, Zembrace Symtouch, rizatriptan, ODT, eletriptan, sumatriptan/naproxen, zolmitriptan ODT

WellCare of North Carolina **Revised Date: August 9, 2021**
Prior Authorization Criteria
Palivizumab

Therapeutic Class Code: W5D
Therapeutic Class Description: Monoclonal Antibody

Medication	Generic Code Number(s)	NDC Numbers(s)
Synagis® 50mg/0.5ml vial	24818	60574411401
Synagis® 100mg/1ml vial	24824	60574411301

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
Early and Periodic Screening, Diagnostic and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount , duration, frequency, location of service, and/or other specific criteria described in the clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies/epsdt-policy-description.

2021/2022 Synagis Criteria
The clinical criteria used by N.C. Medicaid for the 2021/2022 Respiratory Syncytial Virus (RSV) season are consistent with guidance published by the *American Academy of Pediatrics (AAP): 2021 – 2024 Report of the Committee on Infectious Diseases, 32nd-Edition*. This guidance for Synagis use among infants and children at increased risk of hospitalization for RSV infection is available online by subscription. The coverage season is August 15, 2021 through March 31, 2022. Providers are encouraged to review the AAP guidance prior to the start of the RSV season.

Guidelines for Evidenced-Based Synagis Prophylaxis

- Infants younger than 12 months at start of their first RSV season with a diagnosis of:
  - Prematurity - born before 29 weeks 0 days gestation

- Infants in their first RSV season with a diagnosis of:
  - Chronic Lung Disease (CLD) of prematurity (defined as birth at less than 32 weeks 0 days gestation and requiring greater than 21 percent oxygen for at least first 28 days after birth) [**must submit documentation of CLD as defined to meet criteria approval, e.g. NICU discharge summary]**
  - Hemodynamically significant acyanotic heart disease (CHD), receiving medication to control congestive heart failure, and will require cardiac surgical procedures,
  - Moderate to severe pulmonary hypertension
  - Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airways because of ineffective cough
  - Cystic Fibrosis with clinical evidence of CLD and /or nutritional compromise

Note: Infants in their first RSV season with cyanotic heart disease may receive prophylaxis with cardiologist recommendation.

- Infants less than 24 months of age in their second RSV season with a diagnosis of:
  - CLD of prematurity (see above definition) AND continue to require medical support supplemental oxygen, chronic corticosteroid or diuretic therapy) during the six-month period before start of second RSV season
  - Cystic Fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in first year or abnormalities on chest radiography or chest chest computed tomography that persist when stable) or weight-for-length less than10th percentile

- Infants in their first or second RSV Season:
  - With profound immunocompromise during RSV season

- Undergoing cardiac transplantation during RSV season

Coverage Limitations

Coverage of Synagis for CLD, profound immunocompromise, cardiac transplantation and cystic fibrosis will terminate when the beneficiary exceeds 24 months of age.

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, coverage of Synagis should be discontinued due to the extremely low likelihood of a second same season hospitalization <0.5%.

Procedures:

Prior Approval Request

The Synagis® prior authorization (PA) request form is found on the NCTracks pharmacy services page at https://www.nctracks.nc.gov/content/public/providers/pharmacy/pa-drugs-criteria-new-format.html. Submit PA requests by fax to NCTracks at (855) 710–1969. Call the NCTracks Pharmacy PA Call Center at (866) 246–8505 for assistance with submitting a PA request.

Effective this season, document-for-safety is discontinued for Synagis PA submission.

Pharmacy Distributor Information

Use of a point of sale PA override code is not allowed. POS claims should not be submitted by the pharmacy distributor prior to the first billable date of service for the season.

Pharmacy providers should always indicate an accurate days' supply when submitting claims to N.C. Medicaid. Claims for Synagis doses that include multiple vial strengths must be submitted as a single compound-drug claim. Synagis doses that require multiple vial strengths that are submitted as separate individual claims will be subject to recoupment. Physicians and pharmacy providers are subject to audits of beneficiary records by N.C. Medicaid.

Submitting a Request to Exceed Policy

The provider should use the **Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age** to request Synagis coverage outside of policy. The form is available on the NCTracks Prior Approval web page. Information about EPSDT coverage is found on Medicaid's Health Check and EPSDT web page.

WellCare of North Carolina
Pharmacy Prior Approval Request for
Palivizumab (Synagis®)

Beneficiary Information

1. Beneficiary Last Name: _____2. First Name: _____
3. Beneficiary ID #: _____ 4. Beneficiary Date of Birth: _____5. Beneficiary Gender:_____

Prescriber Information

6. Prescribing Provider NPI #: _____
7. Requester Contact Information - Name: _____ Phone #: _____ Ext. _____

Drug Information

8. Drug Name: **Synagis®** 9. Dosage: _____ 10. Quantity Per 30 Days: _____
11. Length of Therapy (in days): ☐ up to 30 Days ☐ 60 Days ☐ 90 Days ☐ 120 Days ☐ 180 Days ☐ 365 Days ☐ Other _____
12. Date of most recent administered dose: _____ ☐ N/A 13.Most recent documented weight: _____

Clinical Information

This is the beneficiary's ☐ first RSV season ☐ second RSV season
Criteria for Infants younger than 12 months at start of their first RSV season
1. Was the beneficiary born premature before 29 weeks 0 days of gestation? ☐ **YES** ☐ **NO**
Birth EGA: _____ Weeks: _____ Days: _____

Criteria for Infants less than 24 months of age in their FIRST RSV Season with one of the following diagnoses
2. Does the beneficiary have one of the following Diagnosis?
- ☐ Hemodynamically significant acyanotic heart disease (CHD), receiving medication to control congestive heart failure, and will require cardiac surgical procedures
- ☐ Moderate to severe pulmonary hypertension
- ☐ Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airways because of ineffective cough
- ☐ Cyanotic heart disease, with cardiologist recommendation. **Submit documentation of cardiologist recommendation**
- ☐ Cystic Fibrosis with clinical evidence of CLD and /or nutritional compromise
- ☐ Profound immunocompromise during RSV season
- ☐ Cardiac transplantation during RSV season
- ☐ Chronic Lung Disease (CLD) of prematurity (defined as birth at less than 32 weeks 0 days gestation and requiring greater than 21% oxygen for at least 28 days after birth)

****Please submit documentation of CLD as defined to meet criteria approval, e.g. NICU discharge summary**

Criteria for Infants less than 24 months of age in their SECOND RSV season with one of the following diagnoses:
3. Does the beneficiary have one of the following Diagnosis?
- ☐ Profound immunocompromise during RSV season
- ☐ Cardiac transplantation during RSV season
- ☐ Cystic Fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in first year or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight-for-length less than10th percentile
- ☐ CLD of prematurity (see above definition) and continue to require medical support supplemental oxygen, chronic corticosteroid or diuretic therapy during the six-month period before start of second RSV season
  Indicate Treatment(s) for CLD:
  ○ chronic corticosteroid therapy ○ diuretic therapy ○ supplemental oxygen ○ no medical support required

****Please submit documentation of CLD as defined to meet criteria approval, e.g. NICU discharge summary**

NOTE: The provider should use the **Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age** to request Synagis outside of policy criteria or for coverage outside the defined coverage period.

Signature of Prescriber: _____ Date: _____
(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

Fax this form to CSRA at (855) 710-1969 Pharmacy PA Call Center: (866) 246-8505