Gateway Health℠ It's Wholecare.

Updated: 08/2020
PARP Approved: 09/2020

Prior Authorization Criteria

Spinal Muscular Atrophy (SMA) Medications

All requests for Spinal Muscular Atrophy (SMA) Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

SMA Medications include Spinraza (nusinersen), Zolgensma (onasemnogene Abeparvovec-xioi), and Evrysdi (risdiplam). New products with this classification will require the same documentation.

For all requests for SMA Medications, all of the following criteria must be met:

- Diagnosis of Spinal Muscular Atrophy
- Prescribed by or in consultation with a neurologist
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- Member has documentation of a baseline evaluation, including a standardized assessment of motor function such as one of the following:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurologic Exam (HINE)
    - Upper limb module (ULM) score
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
    - Six-minute walk test

For Spinraza (nusinersen) all of the following criteria must be met:

- Confirmation of diagnosis by submission of laboratory testing demonstrating corresponding mutations or deletions in chromosome 5q13 that lead to survival motor neuron (SMN) protein deficiency.
- Must not be used concomitantly with Evrysdi
- **Initial Duration of Approval:** 4 months
- **Reauthorization Criteria**
    - Documentation that the patient is responding to the medication based on the prescriber's assessment.
- **Reauthorization Duration of Approval:** 12 months

For Evrysdi (risdiplam) all of the following criteria must be met:

- Member must be 2 months of age or older
- Must have a confirmed diagnosis of 5q-autosomal recessive SMA
- Must not be used concomitantly with Spinraza
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Documentation that the patient is responding to the medication based on the prescriber's assessment
- **Reauthorization Duration of Approval:** 12 months

For Zolgensma (onasemnogene abeparvovec-xioi) all of the following criteria must be met:

- Must be less than 2 years of age
- Documentation of genetic testing confirming bi-allelic *SMN1* deletions or pathogenic variants
- Member is not dependent on invasive ventilation or tracheostomy
- Member must have an anti-AAV9 antibody titer below or equal to 1:50
- The prescriber attests that the member's weight for dosing is confirmed within 14 days of dose administration.
- The prescriber attests that member will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and approximately 30 days following therapy
- Member must not have received this therapy previously
- **Duration of Approval:** Once per lifetime

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
PRIOR AUTHORIZATION FORM – PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Does the member have a confirmed diagnosis of spinal muscular atrophy (SMA)? ☐ Yes ☐ No ICD10 code:_____

Has the member had a baseline assessment of motor milestones? ☐ Yes ☐ No

Please select all that apply and submit documentation of baseline assessment:

- ☐ Hammersmith Functional Motor Scale Expanded (HFMSE)
- ☐ Hammersmith Infant Neurologic Exam (HINE)
- ☐ Upper limb module (ULM) score
- ☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- ☐ Six-minute walk test

For Spinraza:
Has the diagnosis been confirmed by genetic testing? ☐ Yes ☐ No
Will the member be using the medication concomitantly with Evrysdi? ☐ Yes ☐ No

For Evrysdi:
Is there a confirmed diagnosis of 5q-autosomal recessive SMA? ☐ Yes ☐ No
Will the member be using the medication concomitantly with Spinraza? ☐ Yes ☐ No

For Zolgensma:
Has the diagnosis of Spinal Muscular Atrophy (SMA) been confirmed by genetic testing? ☐ Yes ☐ No
Is member dependent on invasive ventilation or tracheostomy? ☐ Yes ☐ No
Does member have an anti-AAV9 antibody titer below or equal to 1:50? ☐ Yes ☐ No
Will the member's weight for dosing be confirmed within 14 days of dose administration? ☐ Yes ☐ No
Will the member receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and approximately 30 days following therapy? ☐ Yes ☐ No
Has the member received Zolgensma previously? ☐ Yes ☐ No

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SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Is the patient responding to the medication (ie. clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment)? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date