EXPERIMENTAL/INVESTIGATIONAL USES

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Experimental or investigational use, as defined below

Prescribing Restriction:

- Prescriber restriction: provider is a board-certified specialist in the area of requested therapy

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

Per Evidence of Coverage (EOC) document page 64, SFHP does not cover experimental or investigational care, defined as care that:

- Is not seen as safe and effective by generally accepted medical standards to treat a condition, or
- Has not been approved by the government to treat a condition

I. Initiation of Therapy:

- Requests not meeting criteria below will be denied per the Investigational/Experimental Section of the PBM-SFHP Prior Authorization (PA) First-Level Review Desktop Procedure as an excluded benefit
- If ALL of the following are met, a request for experimental or investigational use will be reviewed by the SFHP Medical Director
  - The requested therapy is for a life-threatening (likely to cause death unless the couse of disease is interrupted) or seriously debilitating (causes major irreversible morbidity) condition
    - If requested therapy is not for a life-threatening or seriously debilitating condition, utilize “Off-Label Uses” criteria:
      a. No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia AND
      b. Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
      c. Requested use can be supported by at least two published peer reviewed clinical studies
  - The requested therapy is a therapy approved by the FDA
  - Documentation is provided meeting any of the following for each standard therapy for the diagnosis:
    - Trial and failure of standard therapy(ies)
    - Contraindication to standard therapy(ies)
    - Documentation that the requested therapy is likely to be more beneficial to the member than standard therapy(ies):
      a. as evidenced by two documents from medical and scientific evidence (including peer-reviewed medical literature, federal research institutes findings, medical compendia and/or guidelines) OR
      b. as certified in writing by provider, and the provider is an in-network physician
      c. If the request is denied following review by SFHP Medical Director due to not meeting criteria (a) and (b) above, SFHP’s decision will be sent for examination via the independent medical review process for investigational/experimental uses

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to “Initiation of Therapy” section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

- California Health and Safety Code 1370.4, Accessed at https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1370.4.&lawCode=HSC.

Last review/revision date: 10/2020

MEDICATIONS FOR TERMINAL ILLNESS

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Terminal illness, as defined below

Prescribing Restriction:

- Prescriber restriction: provider is a board-certified specialist in the area of requested therapy

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

California Health and Safety Code Section 1368.1 refers to terminal illness as an incurable or irreversible condition that has a high probability of causing death within one year or less.

I. Initiation of Therapy:

- If a request for treatment is for terminal illness as defined above, approve if medication and dose are appropriate based on nature and severity of the terminal illness, and is not considered likely to cause undue harm
  - Criteria above overrides drug-specific criteria and Non-Formulary Medications criteria, when requested for terminal illness
  - If request is for experimental/investigational use in terminal illness, Experimental/Investigational Uses criteria must also be met
- For requests that are denied due to not meeting corresponding criteria above, the following will be provided to the enrollee within five business days of the denial:
  - A statement setting forth the specific medical and scientific reasons for denying coverage
  - A description of alternative treatment, services or supplies covered by the plan, if any

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to “Initiation of Therapy” section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

- California Health and Safety Code 1368.1, Accessed at https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1368.1.&lawCode=HSC.

Last review/revision date: 10/2020

NON-FORMULARY MEDICATIONS

Formulary Status: Non-formulary or Formulary, PA Criteria Required (without specific criteria)

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses^: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.

^HW HMO ONLY: including fertility preservation when a covered treatment may directly or indirectly cause iatrogenic infertility, specifically ovarian stimulation for cryopreservation, or ovarian protection when cryopreservation is not feasible

Prescribing Restriction:

- Quantity Limit* As requested not to exceed FDA approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - For IV medications, if request includes a documented reason why the medication cannot be provided via the Medical Benefit (**Medi-Cal only**), then the request must confirm that the medication is administered by a healthcare professional* AND
  - Drug-specific PA criteria does not exist for the requested drug AND
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND *Off-label criteria^:*
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies

    ^HW HMO ONLY: including fertility preservation when a covered treatment may directly or indirectly cause iatrogenic infertility, specifically ovarian stimulation for cryopreservation, or ovarian protection when cryopreservation is not feasible
  - Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication AND
  - In the absence of evidence supporting use of requested medication compared to preferred agents, documented trial and failure or inability to use all (but no more than 3) available preferred medications indicated for the diagnosis OR
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia OR
  - All other formulary medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy

*Note: capitation deduction may be required, alert Pharmacy Director of approval via this criteria

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

NON-FORMULARY MEDICATIONS
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication AND • Continuation of therapy is medically necessary
References: • DMHC All Plan Letter 20-001 (OPL) Newly Enacted Statues Impacting Health Plans • Practice Committee of the American Society for Reproductive Medicine. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: a committee opinion. Fertility and Sterility. 2019; 112(6): 1022-33. • Oktay K, Harvey BE, Partridge AH, et al. Fertility preservation in patients with cancer: ASCO clinical practice guideline update. J Clin Oncol. 2018; 36: 1994-2001.
Last review/revision date: 4/2021

STEP THERAPY

Formulary Status: Formulary, step therapy required
*For drugs without specific criteria

Coverage Duration: up to indefinite for chronic therapy

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: As requested not to exceed FDA-approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information required for Review

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

I. Approve if:

- Appropriate diagnosis/indication for requested medication or meets off-label criteria below AND
  Off-label criteria:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies
- Documentation is provided that patient has had sufficient prior trial/failure or contraindication/inability to use required step therapy drug(s) OR
- Provider has demonstrated knowledge of step therapy requirements AND
- Medical justification why required step therapy drug(s) would be ineffective or have the potential to cause harm or deterioration of the member's condition OR
- Medical justification why the requested drug would be superior to the required step therapy drug(s)

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria above

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 04/2021

QUANTITY LIMIT EXCEPTION

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: up to indefinite for chronic therapy

Diagnosis Considered for Coverage:

- FDA-approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - Appropriate diagnosis/indication for requested medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Member has a documented treatment failure with the drug prescribed at the quantity limit or requires a dose within prescribing guidelines that exceeds the quantity limit AND
  - Medical justification why the plan's quantity limit will be inadequate based on the member's condition and treatment history AND
  - Dose requested is supported by Medical Compendia, two peer-reviewed trials, or current treatment guidelines

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 4/2021

SAFETY EDIT EXCEPTION

Formulary Status: Formulary, PA or Non-formulary
*For drugs without specific criteria

Coverage Duration: 1 year*
**One month approval for duplication of therapy when transitioning from one agent to another.*

Diagnosis Considered for Coverage:

- Dosing or use in age populations outside of FDA-approved or accepted off-label indications

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose and duration of therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- **For requests exceeding the FDA or compendia max dose, administration frequency or duration of therapy recommendations, approve if:**
  - Patient has documented treatment failure with the drug at the maximum tolerated dose or maximum dose (whichever is the lesser dose), administration frequency or duration of therapy AND
  - Medical justification why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history AND
  - Dose requested is supported by the Medical Compendia, current treatment guidelines, or two peer-reviewed studies
- **For requests for a duplication of therapy**
  - **Transition from one agent to another (**one month only**), approve if:**
    - Provider has outlined a plan to transition member to a similar drug OR
    - Provider has provided a dose titration schedule
  - **Ongoing concurrent therapy with two similar agents, approve if:**
    - Medical justification why treatment with more than one drug in the same class is required based on the patient's condition and treatment history OR
    - Provider has submitted disease state specific standard of care guidelines supporting concurrent therapy
- **For requests exceeding an age restriction, approve if:**
  - Medical justification why the drug is needed outside age limit
  - Indication and dose requested are supported by the Medical Compendia, current treatment guidelines, or two peer-reviewed studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 04/2021

BRAND NAME MEDICATION

Formulary Status: all

Coverage Duration:

- Refer to drug-specific PA criteria OR
- Indefinite for chronic medications OR
- 1 year for non-chronic medications

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit* See drug-specific PA criteria OR As requested not to exceed FDA approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation for failure of generic alternatives

Coverage Criteria:

*SFHP has a mandatory generic policy and requires generic substitution when an equivalent generic product is available.

I. Initiation of Therapy:

- Approve if:
  - The requested medication is in one of the following classes: anti-epileptics, immunosuppressants; OR
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND *Off-label criteria:*
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Trial and failure of at least **two** generic versions of the requested medication by different manufacturers per claims history or documentation from the provider (i.e. dates tried, reason for trial and failure) OR
  - Inability to use at least **two** generic versions of the requested medication by different manufacturers (e.g. two generic versions are not available) AND
  - Documented trial and failure or inability to use up to **three** preferred medications (if available) used to treat the documented diagnosis provided there is no evidence supporting use of the requested non-preferred medication compared to preferred medications

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Clear information provided documenting why generic versions cannot be used

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Clear information provided documenting why generic versions cannot be used.

References: N/A

Last review/revision date: 10/2020

PRIOR AUTHORIZATION EXCEPTION

Formulary Status: Formulary, PA
* Requests for exception to the drug's prior authorization criteria requirements

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose and duration of therapy
- Supporting documentation

Coverage Criteria:

IV. Initiation of Therapy:

- The provider either verbally or in writing has submitted a medical or member-specific reason why prior authorization criteria all or in part is not applicable to the member
  - Medical reasons may include but are not limited to:
    - Criteria requirements are not applicable to the member based on the uniqueness of the member's condition or other physical characteristics of the member's condition.

  OR
  - Member-specific reasons may include but are not limited to:
    - Mental and/or physical characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements.

V. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- Documentation of medical or member-specific why prior authorization criteria all or in part is not applicable to the member (see details in section I above)

VI. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 4/2021

ORAL AND INTRAVENOUS ONCOLYTICS

Formulary Status: Formulary, PA

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-Label indications^: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

  ^HW HMO ONLY: including fertility preservation when a covered treatment may directly or indirectly cause iatrogenic infertility, specifically ovarian stimulation for cryopreservation, or ovarian protection when cryopreservation is not feasible

Prescribing Restriction:

- Authorized quantity: 30 days' supply
- Prescriber restriction: Prescriber must be oncologist or hematologist

Clinical Information Required for Review:

- Diagnosis
- Dose
- Prescriber specialty

Coverage Criteria:

I. Initiation of Therapy:

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) AND
- Documentation is provided of results of genetic testing where required per drug package insert AND
- Documentation is provided of results of all required laboratory values and patient specific information (e.g. weigh, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert AND
- Requested quantity does not exceed FDA approved or standard off-label dose AND
- For IV medications, if request includes a documented reason why the medication cannot be provided via the Medical Benefit (**Medi-Cal only**), then the request must confirm that the medication is administered by a healthcare professional*
- HW HMO ONLY: For use of GnRH agonists for fertility preservation when a covered treatment may directly or indirectly cause iatrogenic infertility, specifically ovarian stimulation for cryopreservation, or ovarian protection when cryopreservation is not feasible, review for coverage using American Society of Clinical Oncology (ASCO) and American Society for Reproductive Medicine (ASRM) criteria

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For IV medications, if documented reason why it cannot be provided via the Medical Benefit (**Medi-Cal only)**: medication is administered by a healthcare professional*

*Note: capitation deduction may be required, alert Pharmacy Director of approval via this criteria)

References:

- NCCN Guidelines® & Clinical Resources. Development and Update of the NCCN Guidelines® Available at: https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed September 4, 2019.
- DMHC All Plan Letter 20-001 (OPL) Newly Enacted Statues Impacting Health Plans
- Practice Committee of the American Society for Reproductive Medicine. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: a committee opinion. Fertility and Sterility. 2019; 112(6): 1022-33.
- Oktay K, Harvey BE, Partridge AH, et al. Fertility preservation in patients with cancer: ASCO clinical practice guideline update. J Clin Oncol. 2018; 36: 1994-2001.

Last review/revision date: 4/2020

SOLID ORAL SUBSTITUTION

Formulary Status: Formulary, age limit (≤12 or 16y) OR non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA-approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: FDA approved or standard off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Dose
- Diagnosis

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Documentation of trial and failure, intolerance, contraindication, or inability (e.g. inability to swallow, etc.) to use **tablet or capsule** formulation

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Continued inability to use **tablet or capsule** formulation of the same medication

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Continued inability to use **tablet or capsule** formulation of the same medication

References: N/A

Last review/revision date: 10/2020

NON-FORMULARY EXTENDED-RELEASE FORMULATION

Formulary Status: Non-formulary

Coverage Duration:
1 year to indefinite depending on drug class (indefinite for chronic use medications, e.g. anticonvulsants)

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: FDA approved or standard off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Documentation of trial and failure, intolerance, contraindication, or inability (e.g. compliance difficulty, etc.) to use **formulary immediate release** formulation if available

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2020

PHYSICIAN-ADMINISTERED MEDICATIONS

Formulary Status: Formulary, PA

Coverage Duration: up to 6 months

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-Label indications: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- None

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria: (applies to Medi-Cal only)

I. Initiation of Therapy:

- Approve if:
  - Medication or product is administered by a healthcare professional AND
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Requested quantity does not exceed FDA approved or standard off-label dose AND
  - Documented reason why it cannot be provided via the Medical Benefit

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Continuation of therapy is clinically appropriate AND
- Medication or product is administered by a healthcare professional AND
- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Continuation of therapy is clinically appropriate AND
- Medication or product is administered by a healthcare professional

References: N/A

Last review/revision date: 10/2020

COMPOUNDED MEDICATIONS

Formulary Status: Non-Formulary/Prior Authorization required

Coverage Duration:
Initial: Not to exceed 3 months
Reauthorization: 6 months

Diagnosis Considered for Coverage:

- Diagnosis appropriate for medications contained in the compounded product

Prescriber Restriction:

- Quantity Limit* 30 day supply

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Current therapy
- Other medications that have been used for diagnosis
- Comorbidities

Coverage Criteria:

I. Initiation Criteria

The plan may authorize coverage of compounded prescription medications with an ingredient cost greater than or equal to $75 when ALL of the following criteria are met:

- The indication, therapeutic amount, and route of administration of each of the active ingredients in the compound are FDA-approved or CMS-recognized compendia supported, AND
- All of the active ingredients included in the compound are FDA-approved medications (bulk chemicals are not FDA approved), AND
- If there are existing clinical coverage criteria for any of the active ingredients, those criteria must also be met for these ingredients, AND
- And <u>one</u> (1) of the following:
  - o There is a current supply shortage of the commercial product, OR
  - o The member has a medical need for a dosage form or dosage strength that is not commercially available, OR
  - o The member had a trial and intolerance to or contraindication to the commercially available product (e.g. allergen/preservative/dye-free, palatability for pediatrics, adverse effects to binders/fillers/other active ingredients), OR
  - o The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Continuation of therapy is clinically appropriate AND
- Prescriber attests that member has been on this medication continuously before joining SFHP

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Continuation of therapy is clinically appropriate

Note: All of the active ingredients included in the compound need to be included on the request for authorization

References: N/A

Last review/revision date: 10/2020

BLOOD PRESSURE MONITORS

Formulary Status:

- Formulary: **(Applies to Medi-Cal and Cal-WRAP only)**
  - Omron 3 Series (NDC 73796-0271-04; 73796-0710-02)
  - Omron 5 Series (NDC 73796-0274-24; 73796-0267-25)
  - Omron 7 Series (NDC 73796-0276-04; 73976-0267-61)
  - Omron 10 Series (NDC 73796-0267-45; 73796-0267-86)
  - Omron (NDC 73796-0267-10)
  - Walgreens Automatic Arm (NDC 11917-0144-84)
  - Walgreens Premium Arm (NDC 11917-0144-87)
  - Walgreens Deluxe Arm (NDC 11917-0144-85)
  - CVS Series 100 (NDC 50428-0535-60)
- Non-formulary:
  - All other monitors

Coverage Duration: One time approval

Diagnosis Considered for Coverage:

- Hypertension

Prescribing Restriction:

- Quantity Limit*: 1 per 5 years (entered as 1 per 30 days)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- n/a

Coverage Criteria: (Applies to Medi-Cal and Cal-WRAP only)

I. Initiation of Therapy:

- For **non-formulary BP monitor,** approve if there is documentation of inability to use formulary BP monitor (e.g. member needs BP monitor with extra-large BP cuff due to upper arm circumference > 17")
- **BP monitors with extra-large cuff:**

Name	Circumference	NDC
Life Source Advanced BP Monitor with Accufit Extra Large Cuff (UA-789AC)	16.5-23.6"	93764-0600-62
Zewa UAM-880DC Deluxe Automatic Blood Pressure Monitor with 2 Cuffs	13.4-18.9"	82891-0388-00

References: N/A

Last review/revision date: 7/2020

NON-FORMULARY BLOOD GLUCOSE METERS

Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies*

Formulary Status:

- Formulary:
  - Accu-Chek Guide Retail Care Kit
- Non-formulary: all other blood glucose meters

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes mellitus type 1 or 2, gestational diabetes

Prescribing Restriction:

- Quantity Limit*: 1 unit per year (365 days)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- Approve if there is documentation of trial and failure or inability to use a formulary blood glucose meter (e.g. Prodigy Voice Blood Glucose Meter is needed due to visual impairment)
- For FreeStyle Libre reader/sensor system, refer to "Blood Glucose Test Strips" criteria
  - i. All other continuous glucose monitoring devices should be requested via the medical benefit

II. Continuation of Therapy for NEW Members (within the last 6 months), refer to "Initiation of Therapy" criteria

References: N/A

Last review/revision date: 4/2021

BLOOD GLUCOSE TEST STRIPS

Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies*

Formulary Status:

- Formulary:
  - Accu-Chek SmartView, Accu-Chek Aviva Plus, Accu-Chek Guide Test Strips
- Formulary, PA required:
  - FreeStyle Libre reader and sensor**
- Non-formulary: all other testing supplies

** All other continuous glucose monitoring devices should be requested via the medical benefit

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes mellitus type 1 or 2, gestational diabetes

Clinical Information Required for Review:

- Diagnosis
- Previous medications

Prescribing Restriction:

- Quantity Limit*:
  - Test strips: #4 strips per day
  - FreeStyle Libre:
    - 3 sensors per 30 days (10-day) or 2 sensors per 28 days (14-day)
    - 1 reader per year

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Coverage Criteria:

I. Initiation of Therapy:

- For **Accu-Chek SmartView, Accu-Chek Aviva Plus, or Accu-Chek Guide test strips over formulary quantity limit,** approve if:
  - Medical need for glucose monitoring more frequent than 4 times daily, or 8 times daily in the case of gestational diabetes (e.g. Frequent hospitalizations, incidents of hypoglycemia, DKA hospitalizations etc.)
- For **FreeStyle Libre** reader/sensor system, approve if:
  - Patient has type I or II diabetes and is on basal + bolus insulin therapy (multiple injections per day) AND
  - There is documentation of medical need for glucose monitoring more frequent than 4 times daily (e.g., frequent hospitalizations, hypoglycemia, DKA, etc.) OR
  - There is documented contraindication/inability to use finger stick testing (e.g., fear of needles)
- For **Contour test strips**, approve if:
  - Test strips will be used with insulin pump
- For **Freestyle Test Strips, Prodigy No Coding Test Strips, Onetouch Ultra Test Strips**, approve if:
  - Trial and failure or inability use formulary strips: Accu-Chek SmartView, Aviva Plus, or Guide

II. For **Continuation of Therapy**, approve

References: N/A

Last review/revision date: 4/2021

LONG-ACTING OPIOIDS

Therapeutic Class: *Analgesics: Opiates, Long-Acting*

Formulary Status:

- Formulary: morphine sulfate ER tablet (MS Contin®)
- PA required:
  - fentanyl transdermal (Duragesic®) 12, 25, 37.5, 50, 62.5, 75, 87.5, 100mcg/h patch
  - oxycodone ER (Oxycontin®) tablet
  - morphine sulfate (Kadian®) 10, 20, 30, 40, 50, 60, 80mg 24h ER capsule
- Non-formulary:
  - buprenorphine (Butrans®) transdermal patch*
  - methadone
  - morphine sulfate (Avinza®) 45, 75, 90, 120mg 24h ER capsule
  - hydromorphone (Exalgo®) 24h ER abuse-deterrent tablet
  - oxymorphone 12h ER tablet
  - MorphaBond® ER (morphine sulfate) 12h ER abuse-deterrent tablet
  - Arymo® ER (morphine sulfate) ER abuse-deterrent tablet
  - Xtampza® ER (oxycodone) 12h ER abuse-deterrent tablet
  - Nucynta® (tapentadol) 12h ER tablet

Excluded for Medi-Cal (covered by fee-for-service (FFS) Medi-Cal as a carve-out)

Coverage Duration:

- For non-preferred/non-formulary drugs: for duration requested up to one year
- For regimens > 500 MME/day: for hospice/cancer pain, indefinite; for non-cancer pain, up to one year

Diagnosis Considered for Coverage:

- Chronic pain
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit:*
  - morphine sulfate ER tablets: #90 per 30 days
  - buprenorphine patch: #4 patches per 28 days
  - fentanyl patch: #15 patches per 30 days
  - oxycodone ER, oxymorphone ER, Nucynta® ER, Xtampza® ER, MorphaBond® ER, Arymo® ER: #60 per 30 days
  - methadone: #180 per 30 days (up to 60 mg/day)
  - morphine sulfate 24h caps, hydromorphone ER: #30 tablets per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
- For **fentanyl patches, morphine sulfate ER caps, oxycodone ER,** approve if:
  - there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **morphine sulfate ER tablets at an adequate (equianalgesic) dose** OR
  - there is documentation of pain caused by active cancer

LONG-ACTING OPIOIDS

- For **methadone** or **buprenorphine patch (HW HMO only)**, approve if:
  - Diagnosis of pain
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following alternatives AND
    - short-acting opiates AND
    - morphine sulfate ER tablets AND one other long-acting opioid at an adequate (equianalgesic) dose
  - Naloxone has been prescribed for the member
- For **hydromorphone ER, Nucynta ER®**, or **oxymorphone ER**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use ALL of the following alternatives at an adequate (equianalgesic) dose
    - Oxymorphone immediate release AND
    - Morphine sulfate ER tablets or capsules AND
    - Fentanyl patches AND Oxycodone ER
- For total opioid regimens above 500 morphine milligram equivalents per day, approve if:
  - If request is for non-formulary medication, criteria for (B) above are met AND
  - One of the following is met:
    - Regimen is prescribed by or under the supervision of a hospice/palliative care specialist OR
    - Regimen is for pain caused by active cancer OR
    - Regimen is for chronic non-cancer pain and **all** of the following are met:
      a. Member has been referred to a pain management specialist
      b. Non-pharmacologic treatments (e.g., acupuncture, physical therapy, chiropractic adjustment, etc.) have been discussed with the member and/or the member has tried and failed appropriate non-pharmacological alternatives for pain
      c. Member has had trial and failure, intolerance of, or contraindication to **at least two** non-opioid analgesics (e.g. acetaminophen, NSAIDs, select anticonvulsants and antidepressants if indicated for neuropathy or fibromyalgia)
      d. Documentation is provided that the prescribing provider has reviewed CURES database for the member, and the member is not receiving opioids from any other prescriber outside the requesting provider's practice
      e. Documentation is provided that the prescriber reviewed the potential risks of ultra-high dose opioid use with the member
      f. Documentation is provided that the prescriber has evaluated the member's treatment history for evidence of benefit with opioid titration in terms of function as well as pain score goals
      g. Documentation is provided that the member has received a prescription for naloxone and education for use
      h. Documentation is provided that urine drug screens are being utilized to assess for illicit drug use and/or compliance
      i. The provider attests that the member has no known opioid overdose episodes in the last year (i.e., hospitalizations or use of naloxone)
      j. If the member is currently on a benzodiazepine (filled in the last 6 months), documentation is provided of a plan to taper the benzodiazepine and that the prescriber reviewed risks of combination opioid-benzodiazepine use
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months):

- Refer to "Initiation of Therapy" section but:
  - approve up to 2 months on non-preferred medication to allow transition to preferred agents
  - approve up to 6 months on opioid regimens >500 morphine milligram equivalents per day to allow evaluation for tapering protocol and/or non-opioid treatment

LONG-ACTING OPIOIDS
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if patient is stable and continuing the medication
References: • CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Recommendations and Reports / March 18, 2016 / 65(1); 1–49. Accessed at http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm • State of California-- Health and Human Services Agency, Department of Health Care Services. All Plan Letter 19-012. https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2019/APL19-012.pdf. Revised 11/15/2019.
Last review/revision date: 1/2021

SHORT-ACTING OPIOIDS

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary:
  - codeine tablet (age minimum, 12 yo)
  - hydromorphone (Dilaudid®) tablet
  - morphine sulfate (MS-IR®) tablet
  - oxycodone (Roxicodone®) tablet
  - tramadol (Ultram®) 50mg tablet (age minimum, 18 yo)
  - codeine phosphate-acetaminophen (Tylenol w/codeine®) tablet (age minimum, 12 yo)
  - hydrocodone-acetaminophen (Vicodin®) 2.5-325, 5-325, 7.5-325, 10-325mg tablet
  - oxycodone-acetaminophen (Percocet®) 2.5-325, 5-325, 7.5-325, 10-325mg tablet
  - acetaminophen with codeine (Tylenol-Codeine #3®) 300-30mg tablet (age minimum, 12 yo)
  - acetaminophen with codeine (Tylenol-Codeine #4®) 300-60mg tablet (age minimum, 12 yo)
  - acetaminophen with codeine (Capital with codeine®) 300-15mg tablet (age minimum, 12 yo)
  - tramadol-acetaminophen (Ultracet®) 37.5-325mg tablet (age minimum, 18 yo)
  - oxymorphone tablet
  - morphine sulfate 10, 20, 100mg/5mL solution
  - oxycodone 5mg/5mL solution
  - oxycodone 20mg/mL oral concentrate
  - acetaminophen with codeine 120-12mg/5mL solution (age minimum, 12 yo)
  - acetaminophen with codeine 120-12mg oral suspension (age minimum, 12 yo)

Coverage Duration:

Initial days' supply > 7 days: one-time only
Subsequent quantity above listed limit: for duration requested up to one year
For regimens > 500 MME/day: for hospice/cancer pain, indefinite; for non-cancer pain, up to one year
Non-formulary drug: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain, chronic pain
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - *Initial fill <u>day supply</u> limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days for products listed below:*
    - codeine tablet
    - hydromorphone (Dilaudid®) tablet
    - morphine sulfate (MS-IR®) tablet
    - oxycodone (Roxicodone®) tablet
    - codeine phosphate-acetaminophen (Tylenol w/codeine®) tablet
    - hydrocodone-acetaminophen (Vicodin®) 2.5-325, 5-325, 7.5-325, 10-325mg tablet
    - oxycodone-acetaminophen (Percocet®) 2.5-325, 5-325, 7.5-325, 10-325mg tablet
    - acetaminophen with codeine (Tylenol-Codeine #3®) 300-30mg tablet
    - acetaminophen with codeine (Tylenol-Codeine #4®) 300-60mg tablet
    - acetaminophen with codeine (Capital with codeine®) 300-15mg tablet
    - tramadol-acetaminophen (Ultracet®) 37.5-325mg tablet
  - *Subsequent fill quantity limit: #240 units per 30 days for products listed below:*
    - tramadol (Ultram®) 50 mg tablet
  - *Subsequent fill quantity limit: #360 units per 30 days for products listed below:*
    - morphine sulfate 10, 20, 100mg/5mL solution
    - oxycodone 5mg/5mL solution
    - oxycodone 20mg/mL oral concentrate

SHORT-ACTING OPIOIDS

- acetaminophen with codeine 120-12mg/5mL solution
- acetaminophen with codeine 120-12mg oral suspension

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
- For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
  - Medication is prescribed by a practitioner involved with care of the diagnosis provided AND
  - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met (see A below)
  - If medication is non-formulary, criteria for that drug are met (see B below) AND
  - One of the following:
    - Member has history of opioid use within the last 180 days documented through IPNS or CURES, or documented by requesting physician if member was on opioids out of state OR
    - Indication of cancer pain OR
    - Indication of palliative care OR
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease) OR
    - expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
- (A) For requests for formulary medication over subsequent fill quantity limit, approve if:
  - Use is short-term (i.e. less than 6 months requested) for post-operative or acute injury pain OR
  - Indication of chronic cancer pain OR
  - There is failure with or inability to use long-acting opiates (e.g. morphine sulfate ER tablets) OR
  - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates
- (B) For non-formulary medications, approve if:
  - For requests for non-formulary strength of oxycodone-APAP or hydrocodone-APAP, documentation of trial or failure or inability to use oxycodone-APAP 5-325mg or formulary hydrocodone-APAP (e.g. total daily APAP dose exceeded, unable to split tablets, etc.) or inability to use oxycodone and APAP as separate ingredient products
  - For requests for other non-formulary medications, approve if:
    - Documented trial and failure, intolerance, contraindication, or inability to use all (but no more than 3) available preferred medications indicated for the diagnosis OR
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - If the request is for a liquid oral or rectal dosage form, documentation of trial and failure, intolerance, contraindication or inability (e.g., inability to swallow, etc.) to use tablet or capsule formulation
- For total opioid regimens above 500 morphine milligram equivalents per day, approve if:
  - If request is for non-formulary medication, criteria for (B) above are met AND
  - One of the following is met:
    - Regimen is prescribed by or under the supervision of a hospice/palliative care specialist OR
    - Regimen is for pain caused by active cancer OR
    - Regimen is for chronic non-cancer pain and **all** of the following are met:
      a. Member has been referred to a pain management specialist
      b. Non-pharmacologic treatments (e.g., acupuncture, physical therapy, chiropractic adjustment, etc.) have been discussed with the member and/or the member has tried and failed appropriate non-pharmacological alternatives for pain
      c. Member has had trial and failure, intolerance of, or contraindication to **at least two** non-opioid analgesics (e.g. acetaminophen, NSAIDs, select anticonvulsants and antidepressants if indicated for neuropathy or fibromyalgia)
      d. Documentation is provided that the prescribing provider has reviewed CURES database for

SHORT-ACTING OPIOIDS

the member, and the member is not receiving opioids from any other prescriber outside the requesting provider's practice

e. Documentation is provided that the prescriber reviewed the potential risks of ultra-high dose opioid use with the member
f. Documentation is provided that the prescriber has evaluated the member's treatment history for evidence of benefit with opioid titration in terms of function as well as pain score goals
g. Documentation is provided that the member has received a prescription for naloxone and education for use
h. Documentation is provided that urine drug screens are being utilized to assess for illicit drug use and/or compliance
i. The provider attests that the member has no known opioid overdose episodes in the last year (i.e., hospitalizations or use of naloxone)
j. If the member is currently on a benzodiazepine (filled in the last 6 months), documentation is provided of a plan to taper the benzodiazepine and that the prescriber reviewed risks of combination opioid-benzodiazepine use

- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), refer to "Initiation of Therapy" section

- Refer to "Initiation of Therapy" section but:
  - approve up to 2 months on non-preferred medication to allow transition to preferred agents
  - approve up to 6 months on opioid regimens >500 morphine milligram equivalents per day to allow evaluation for tapering protocol and/or non-opioid treatment

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit (A) are met

References:

- CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Recommendations and Reports / March 18, 2016 / 65(1); 1–49. Accessed at http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
- State of California-- Health and Human Services Agency, Department of Health Care Services. All Plan Letter 19-012. https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2019/APL19-012.pdf. revised 11/15/2019.

Last review/revision date: 1/2021

ENTERAL NUTRITION PRODUCTS

Standard/Specific Therapeutic Class: *Electrolytes & Miscellaneous Nutrients; Miscellaneous Dietary Supplements*
Formulary Status: Formulary, PA required **(Applies to Medi-Cal and Medicare/Medi-Cal only)**

Coverage Duration: 6 months for all indications except indefinite where chronic tube feeding is needed (e.g. short gut syndrome, severe cerebral palsy or other chronic encephalopathy)

Diagnosis Considered for Coverage:
- In adults: weight loss
- In children: failure to thrive

Prescribing Restriction:
- Quantity Limit*
  - Liquid #21,330 mL per 30 days (3 cans of 237mL/can per day)
  - Powder #4,540 grams per 30 days (32oz or 153.6gm per day; 10 cans of 454 gm/can)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:
- Diagnosis
- Weight documentation (e.g. BMI, recent weight trends, etc.)
- Volume

Coverage Criteria: (Applies to Medi-Cal and Medicare/Medi-Cal only)

I. Initiation of Therapy, approve if:
- Documentation is dated within 3 months of the request AND
- For **Standard Products** (e.g. Boost, Compleat, Core Essentials, Duocal, Ensure, Fibersource, IMPACT, Isosource, Jevity, Nutren, Osmolite, PediaSure, Promote, Replete, Resource, TwoCal) ONE of the following applies:
  - For members ≥ 21 years of age:
    - There is documented medical condition AND
    - There is inability to meet nutritional needs with dietary adjustment or altered-consistency (soft/pureed) foods (e.g. member has decreased nutritional intake due to cancer diagnosis) AND
    - There are clinical indicators of nutritional risk (see definition below)

      Nutritional risk is defined as:
      - ***Involuntary weight loss ≥ 10% of usual body weight within 6 months***
      - ***Involuntary weight loss ≥ 7.5% of usual body weight within 3 months***
      - ***Involuntary weight loss ≥ 5% of usual body weight in 1 month***
      - ***BMI < 18.5 kg/m^2***
  - OR, for members < 21 years of age:
    - Diagnosis of failure to thrive AND
    - For children 12-24 months:
      - Weight or BMI ≤ 3rd percentile OR
      - Weight or BMI ≤ 5th percentile AND one of the following:
        - Product is recommended by GI specialist or nutrition specialist OR
        - Patient has a physiological or behavioral disorder responsible for low weight
    - For children and adolescents 2-20 years of age:
      - Weight or BMI ≤ 5th percentile
  - OR there is documentation of severe swallowing or chewing difficulty (e.g. due to cancer in the mouth/throat/esophagus, injury/trauma/surgery/radiation therapy in head or neck, chronic neurological disorders, severe craniofacial anomalies)
  - OR There is documented medical diagnosis requiring enteral nutrition products administered via feeding tube
  - OR Member is transitioning from parenteral or enteral tube feeding to oral diet
- For **Specialized Enteral Products**, approve if:
  - Criteria for Standard Products listed above are met AND
  - For diabetic products (e.g. Boost Glucose Control, Diabetisource Ac, Glucerna, Glytrol): there is documented diagnosis of hyperglycemia or diabetes
  - For renal products (e.g. Nepro with Carb Steady, Novasource Renal, Renalcal, Renastart Suplena with Carb

ENTERAL NUTRITION PRODUCTS

Steady,): there is documented diagnosis of chronic renal disease or abnormal renal indicators within 6 months of the request (e.g. blood serum potassium, BUN, urine creatinine, GFR)
    - For hepatic products (e.g. Nutrihep): there is documented liver disease or abnormal LFTs within 6 months of the request
    - For carbohydrate modular products (e.g. Benecalorie, Duocal, Polycal): there is inability to meet caloric nutritional need with current use of an enteral nutrition product
    - For lipid(fat) modular products (e.g. Betaquik, Carbzero, Duocal, Lipistart, Liquigen, MCT OIL, MICROLIPID): there is documented diagnosis of inability to digest or absorb conventional fats or uncontrolled seizure disorder that cannot be medically managed
    - For protein modular products (e.g. BENEPROTEIN, LiquaCel, ProCel, Promod, Pro-Stat): there is documented inability to meet protein requirement with current use of high protein enteral nutrition product
- For **Elemental and Semi-elemental Enteral Products** (e.g. Alfamino Junior, Core Essentials Pediatric Peptide, EleCare Jr, EO28 Splash, Impact Peptide, Neocate, PediaSure Peptide, Pepdite Junior, Peptamen, Perative, Pivot, PurAmino, Tolerex, Vital, Vivonex,) approve if there is documentation of one of the following:
    - Intestinal malabsorption diagnosis (ICD-10-CM codes K90.0 – K90.9 and K91.2) OR
    - Chronic medical diagnosis with trial and failure or contraindication to specialized disease-specific enteral nutrition product AND inability to absorb nutrients or tolerate intact protein that cannot be medically managed
- For **Metabolic Products** (e.g. Complete Amino Acid Mix, Complex, Glytactin, Lophlex, Milupa, PhenylAde, PKU, Tylactin, etc.), approve if:
    - Diagnosis of inborn errors of metabolism (see DHCS Criteria in the reference section for ICD-10 codes)

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:
- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- Continuation of therapy is medically necessary (e.g. weight still below goal or therapy is needed to maintain healthy weight)

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:
- Continuation of therapy is medically necessary (e.g. weight still below goal or therapy is needed to maintain healthy weight)

References:

- California Department of Health Care Services. Provider Manual: Enteral nutrition products. https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral.pdf. Updated August 2020. Accessed 10/2/2020.

Last review/revision date: 4/2021

SPECIALTY INFANT/TODDLER ENTERAL PRODUCTS

Standard/Specific Therapeutic Class: *Infant Formulas*
Formulary Status: Formulary, PA required

Coverage Duration:
Premature infants:
Initial: up to 6 months of corrected age
Renewal: up to 1 year of corrected age
Cow milk protein allergy: up to max age of use per product labeling

Diagnosis Considered for Coverage:
- Prematurity
- Cow milk allergy

Prescribing Restriction:
- Quantity Limit*
  - Liquid: up to #42,660 mL per 30 days (180 cans per 30 days (237 ml per can))
  - Powder: up to #9,080 grams per 30 days (64 ounces per day (4.5 grams per ounce of formula; quantity in grams per can differs by product))

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:
- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:
- For products for **premature infants** (e.g. EnfaCare, Enfamil, Similac NeoSure, Similac Special Care), approve if:
  - Documentation of gestational age (< 37 weeks) or birth weight less than 3500 grams AND
  - Member is less than one year of corrected age AND
  - For Alimentum, Pregestimil, Nutramigen: cow milk protein allergy (e.g. blood in stool, eczema) AND inability to use non-cow's milk protein-based formula (i.e. soy-based formula)
- For hydrolyzed products for **cow milk protein allergy** (e.g. Gerber Good Start Extensive HA, Nutramigen, Pregestimil, Similac Alimentum), approve if:
  - Member is appropriate age for the requested product per product labeling AND
  - There is documentation of cow milk protein allergy OR
  - There is documentation of severe food allergy indicating a sensitivity to intact protein AND
- For amino-acid based products for **cow milk protein allergy** (e.g. Alfamino, EleCare Infant, Neocate Infant, PurAmino), approve if:
  - Member is appropriate age for the requested product per product labeling AND
  - Member has inability to use infant formula due to one of the following, OR:
    - There is documentation of cow milk protein allergy OR multiple food protein allergies OR eosinophilic GI disorder
    - Protein maldigestion or malabsorption diagnosis where hydrolyzed products have been tried and failed
    - Diagnosis of short bowel syndrome
  - Documentation of trial and failure or contraindication to hydrolyzed products
- For renal products (Similac PM), approve if member has documentation of renal function impairment, hypercalcemia, or hypocalcemia due to hyperphosphatemia
- For Chylothorax or LCHAD deficiency products (Enfaport RTU), approve if member has documentation of one of the following:
  - Chylothorax
  - Long-chain-3-hydroxyacyl-CoA-dehydrogenase deficiency
  - Cystic fibrosis
  - Mitochondrial disorder

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:
- Prescriber attests that member has been on this medication continuously before joining SFHP AND

SPECIALTY INFANT/TODDLER ENTERAL PRODUCTS
• Request is for generic or single source brand AND • There is documented justification for why continuation of therapy is medically necessary **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • There is documented justification for why continuation of therapy is medically necessary
References: • Vandeplas Y. et al. Guidelines for the diagnosis and management of cow's milk protein allergy in infants. Arch Dis Child. 2007 Oct; 92(10): 902–908. • LaHood A, et al. Outpatient Care of the Premature Infant Am Fam Physician. 2007 Oct 15;76(8):1159-1164. • California Department of Health Care Services. https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral.pdf. Updated 8/2020. Accessed 10/2/2020.
Last review/revision date: 10/2020