Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Non-Formulary Exceptions

Effective: July 1, 2025

Guideline Type	☐ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

These coverage guidelines are designed to provide a systematic approach to review formulary exception requests.

Drugs that are Non-formulary are not covered because there are safe, comparably effective alternatives or generic versions of the brand-name drugs available and covered on our formularies.

Clinical Guideline Coverage Criteria

The plan may authorization a formulary exception of a non-formulary medication when **ALL** of the following criteria are met:

Multisource Brand with a Therapeutically Equivalent Generic or Non-formulary Generic Drug

Note: This coverage criteria does not apply to multisource brand hormonal contraceptives with a therapeutically equivalent generic.

1. The requested medication has a diagnosis that is one of the following:
    a. An Food Drug Administration (FDA)-approved indication
    b. A medically accepted indication that is supported by nationally recognized compendia

AND

2. Documentation of **one (1)** of the following:
    a. Documentation of **both** of the following:
        i. The patient has had a treatment failure of two (2) or more formulary alternative medications within the same therapeutic class (where coverage is listed on the formulary as applicable), including the therapeutically equivalent generic or the preferred brand (where coverage is listed on the formulary as applicable)
        ii. The patient has an allergy to an ingredient in the therapeutically equivalent generic product or preferred brand that is not contained in the multi-source brand or non-formulary generic alternative

OR

    b. The medication is requested due to a drug shortage

OR

    c. Clinical rationale that a change to the formulary alternative would result in instability of the medical condition (e.g., narrow therapeutic index medications)

AND

3. If the formulary alternative medication(s) is covered with prior authorization, documentation the patient meets the current coverage criteria for the formulary alternative medication(s)/therapeutic class

Single Source Brand

(Note: This coverage criteria does not apply to drugs listed below that have drug specific guidelines (e.g. Vuity))

1. The requested medication has a diagnosis that is one of the following:
    a. An Food Drug Administration (FDA)-approved indication
    b. A medically accepted indication that is supported by nationally recognized compendia

AND

2. Documentation the patient has had a treatment failure of two (2) or more formulary alternative medications within the same therapeutic class (where coverage is listed on the formulary as applicable)

AND

3. Documentation of one (1) of the following (when applicable):
    a. If the formulary alternative medication(s) is covered with prior authorization, documentation the patient meets the current coverage criteria for the formulary alternative medication(s)/therapeutic class
    b. If there are no formulary alternatives and if the plan has drug specific coverage criteria, documentation the patient meets those criteria for the requested medication
    c. If the non-formulary drug is a novel agent, defined as a “first of its kind drug” in a new class of drugs, then the following must be met:
        i. Documentation from the requesting physician showing that all other available lines of treatment that are consistent with generally accepted principles of professional medical practice and/or with guidelines from a nationally recognized entity for the disease for which the patient is being treated, have been exhausted
    d. If the request is for a nonformulary diabetic test strip or nonformulary insulin, the requesting physician has documented that the patient is actively using a continuous subcutaneous insulin infusion pump that requires the use of the nonformulary diabetic test strip or insulin as medically necessary

Opioid analgesics (in addition to criteria above):

The plan may authorize coverage of opioid analgesic medications which are Non-formulary, when all the following criteria are met:

Initial Criteria:

1. Both of the following:
    a. The patient is diagnosed with sickle-cell, cancer-related, or end-of-life pain

OR

2. **ALL** of the following:
    a. The patient has a diagnosis of pain

AND

    b. The patient signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

    c. The patient has tried and failed a generic short acting opioid, if the request is for a long-acting opioid

AND

    d. The risks of use of a high dose schedule II, III, or IV analgesic use (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the patient

AND

    e. The provider has a plan to monitor for signs of misuse, abuse, and addiction during therapy

***Reauthorization Criteria*:**

1. Both of the following:
    a. The patient is diagnosed with sickle-cell, cancer-related, or end-of-life pain

OR

2. **ALL** of the following:
    a. The patient has a diagnosis of pain

AND

    b. The patient signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

    c. The risks of use of a high dose schedule II, III, or IV analgesic use (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the patient

AND

d. The provider has a plan to monitor for signs of misuse, abuse, and addiction during therapy

Brand Hormonal Contraceptives

1. Documentation of **one (1)** of the following:
   a. The patient has had a treatment failure of two (2) or more formulary alternative medications within the same therapeutic class, including the therapeutically equivalent generic when applicable
   b. If the request is for a multi-source brand, the patient has an allergy to an ingredient in the therapeutically equivalent generic product that is not contained in the multi-source brand
   c. Clinical justification that a change to the therapeutically equivalent generic, or a formulary alternative, would result in instability of the medical condition
   d. The request for the multisource brand medication is due to a drug shortage
   e. A clinical rationale is provided that a covered formulary alternative is not clinically appropriate

Drug Specific Formulary Exception Guidelines:

Vuity (pilocarpine HCl)

Initial Authorization

The plan may authorize coverage of **Vuity (pilocarpine)** for patients when **ALL** the following criteria are met:

1. Documented diagnosis of presbyopia

AND

2. The prescriber is an optometrist or ophthalmologist, or a specialist consult note is provided

AND

3. The patient is 40 years of age or older

AND

4. Documentation of a clinical rationale for not using, or a contraindication to the use of corrective lenses

Reauthorization

1. Documentation of a clinical rationale for not using, or a contraindication to the use of corrective lenses

AND

2. Documentation of positive clinical response to therapy

Abilify MyCite (aripiprazole tablet with sensor)

The plan may authorize coverage of **Abilify MyCite** for patients when **ALL** the following criteria are met:

1. Patient is 18 years of age or older

AND

2. Documented diagnosis of one of the following: bipolar disorder, schizophrenia, major depressive disorder

AND

3. Patient has a history of poor adherence (<80%) with at least two oral second generation antipsychotics (e.g., risperidone), one of which must be aripiprazole

AND

4. Documentation of treatment failure with or intolerance to a long acting injectable aripiprazole formulation, or documentation of clinical rationale that a long acting injectable aripiprazole formulation is not medically appropriate for this patient

AND

5. Documentation that the low medication adherence rate with aripiprazole was not related to an inadequate response, intolerance, or adverse effect

AND

6. Documentation that the patient has experienced worsening symptoms due to lack of adherence with oral second-generation antipsychotics (e.g., risperidone)

AND

7. Documentation that the patient has attempted all of the following strategies to improve adherence:
   - Use of pillboxes
   - Setting reminder alarms

- Coordinating the administration time with that of other daily medications

AND

8. Documentation of a comprehensive treatment plan that will incorporate the data from the mobile application/web-based portal to monitor the patient's treatment

Wegovy (semaglutide) for Secondary Cardiovascular Prevention in Overweight or Obesity

Initial Authorization:

For formularies subject to non-formulary review, the plan may authorize coverage of **Wegovy (semaglutide)** for patients when **ALL** the following criteria are met:

1. Patient is 45 years of age or older

AND

2. Patient has established cardiovascular disease as evidenced by one of the following:
    a. Prior myocardial infarction (MI)
    b. Prior stroke
    c. Peripheral arterial disease ((i.e., intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)

AND

3. Patient has BMI of 27 or greater

AND

4. Used in as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND

5. Patient is on standard of care therapy from each of the following classes unless there is a contraindication or intolerance:
    a. Cholesterol lowering medication (e.g., statin)
    b. Antihypertensive (e.g., ACE inhibitor, ARB, beta blocker)
    c. Antiplatelet agent (e.g., aspirin, clopidogrel)

AND

6. Patient does not have either of the following:
    a. Diagnosis of type 2 diabetes
    b. New York Heart Association (NYHA) class IV heart failure

Reauthorization:

1. Member is adherent to therapy as defined by having consistently filled it over the past 4 months

AND

2. Member is currently on a maintenance dose of 1.7 mg or 2.4 mg once weekly

AND

3. Patient has established cardiovascular disease as evidenced by one of the following:
    a. Prior myocardial infarction (MI)
    b. Prior stroke
    c. Peripheral arterial disease ((i.e., intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)

AND

4. Used in as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND

5. Patient continues on standard of care therapy from each of the following classes unless there is a contraindication or intolerance:
    a. Cholesterol lowering medication (e.g., statin)
    b. Antihypertensive (e.g., ACE inhibitor, ARB, beta blocker)
    c. Antiplatelet agent (e.g., aspirin, clopidogrel)

AND

6. Patient does not have either of the following:

a. Diagnosis of type 2 diabetes
b. New York Heart Association (NYHA) class IV heart failure

Zepbound (tirzepatide) for Moderate-to-Severe Obstructive Sleep Apnea in Obesity

Initial Authorization:

For formularies subject to non-formulary review, the plan may authorize coverage of **Zepbound (tirzepatide)** for patients when **ALL** the following criteria are met:

1. Patient is 18 years of age or older

AND

2. Patient has documented diagnosis of moderate-to-severe obstructive sleep apnea defined as apnea-hypopnea index (AHI) ≥15 events per hour on sleep study using the AASM 1B hypopnea scoring method, when there is ≥4% oxygen desaturation from pre-event baseline (Medicare criteria), completed in the last 365 days (submission of sleep study using the AASM 1B hypopnea scoring method (Medicare criteria), when there is ≥4% oxygen desaturation from pre-event baseline, showing AHI ≥15 in the past 365 days required)

AND

3. Patient has BMI of 30 or greater

AND

4. Prescribed by a sleep specialist

AND

5. Patient had history of unsuccessful dietary effort to lose body weight

AND

6. Used in as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND

7. One of the following:
   a. Patient has been evaluated and counseled on continuous positive airway pressure (CPAP) therapy as the preferred treatment of choice
   b. Patient is not a candidate for CPAP therapy (e.g., upper airway anatomic abnormalities, etc.)

AND

8. Patient does not have either of the following:
   a. Diagnosis of type 2 diabetes
   b. New York Heart Association (NYHA) class IV heart failure

Reauthorization:

1. Patient demonstrates positive clinical response to therapy (e.g., patient reports less daytime sleepiness, decrease in respiratory events per hour of sleep)

AND

2. Patient is currently on a maintenance dose of 10 mg or 15 mg once weekly

AND

3. Used in as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND

4. Submission of chart note or medical record with baseline and follow-up weights, confirming one of the following:
   a. Patient has been receiving Zepbound therapy for up to 6 months and has had a weight loss of greater than or equal to 5% of baseline body weight
   b. Patient has been receiving Zepbound therapy for greater than 6 months and is continuing to experience or maintain weight loss

AND

5. Patient does not have either of the following:
   a. Diagnosis of type 2 diabetes
   b. New York Heart Association (NYHA) class IV heart failure

Limitations

1. Duration of coverage will be based on the following:
    - Formulary exceptions due to drug shortages will be authorized for three (3) months.
    - Formulary exceptions of opioid analgesics will be authorized for an initial duration of six (6) months and twelve (12) months upon reauthorization, with the exception of a diagnosis of sickle-cell, cancer-related, or end-of-life pain, where twelve (12) months will be authorized.
    - Formulary exceptions for multisource brand hormonal contraceptives will be authorized for life of plan.
    - Formulary exceptions for Vuity will be authorized for 12 months.
    - Formulary exceptions for Wegovy for secondary cardiovascular prevention in overweight/obesity will be authorized for an initial duration of six (6) months and twelve (12) months upon reauthorization.
    - Formulary exceptions for Zepbound for moderate-to-severe obstructive sleep apnea in obesity will be authorized for an initial duration of six (6) months and twelve (12) months upon reauthorization.
    - All other formulary exceptions:
        - The specified duration of approval in existing prior authorization programs for the requested drug or formulary alternative(s)/therapeutic class
        - The length of treatment as allowed per the Food and Drug Administration package labeling of the requested medication
2. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.
3. Over-the-counter (OTC) products may be excluded from coverage, per plan benefit documents. The only OTC products that are covered, are those that are listed on the formulary.
4. Coverage of non-formulary hormonal contraceptives:
    - All non-formulary contraceptives should be covered at $0 cost share.
    - The coverage criteria for Hormonal Contraceptive does not apply to members of “grandfathered” plans and certain religious group employers that are exempt from the requirement to cover contraceptive services.
    - The coverage criteria for Hormonal Contraceptives do not apply to contraceptive agents that require administration by a health care professional (e.g. intramuscular injections, intrauterine devices), and non-hormonal contraceptives (e.g. diaphragms, condoms)
5. Medications or products excluded from pharmacy coverage will not be reviewed against the Non-Formulary Exception pharmacy Medical Necessity Guideline.
6. Drugs that do not have reliable scientific evidence demonstrating that the treatment is effective in improving health outcomes or that appropriate patient selection has been determined will not be approved, even if approved for lawful marketing by the U.S. Food and Drug Administration.
7. Drugs that are unproven and not medically necessary for the treatment of their FDA approved indication due to insufficient evidence of efficacy will not be approved.
8. Documentation of a patient having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.
9. For applicable formularies, failure of an adequate 6-month trial of preferred weight loss medication is defined as lack of 5% weight reduction, as documented by 2 separate weights at least 4 months apart while on the medication or unacceptable side effects from the medication.
10. If a formulary alternative is available in member’s age range, documentation that the member has had a treatment failure to the formulary alternative, as appropriate.
11. Narrow Therapeutic Index Agents:

Multi-source brand medications with narrow therapeutic index	
CellCept	Neurontin
Coumadin	Prograf
Depakene, Depakote	Rapamune
Felbatol	Sandimmune
Gabitril	Spritam
Lanoxin	Tegretol
Lamictal	Topamax
Lithobid	Trileptal
Mysoline	Zarontin
Neoral	

Codes

None

References

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3. Wegovy (semaglutide) [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S. November 2024.
4. Zepbound (tirzepatide) [package insert]. Indianapolis, IN: Lilly USA, LLC. December 2024.
5. Centers for Disease Control and Prevention (CDC). Injury prevention & control: opioid overdose. URL: cdc.gov/drugoverdose/pubs/index.html#tabs-760094-4. May 9, 2023. Accessed 2023 June.
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8. NCQA, HEDIS Measures and Technical Resources, Risk of Continued Opioid Use URL: Risk of Continued Opioid Use – NCQA, Accessed June 2023.
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Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- July 11, 2023: Effective October 1, 2023, updated opioid analgesic criteria and approval duration: Added criteria requirement requiring a trial with a short-acting opioid, if the request is for a long-acting opioid, and updated approval duration in the limitations section: 12 months for a diagnosis of sickle-cell, cancer-related, or end-of-life pain and 6 months for all other initial opioid requests, and 12 months upon reauthorization.
- September 12, 2023: Effective October 1, 2023, clarified requirement with generic immediate-release opioid for long-acting opioid criteria.
- November 14, 2023: Effective February 1, 2024, added limitation that excluded medications will not be reviewed against the Non-Formulary Exceptions MNG and medications that do not have clinical efficacy or that appropriate patient selection has not been determined, may not be approved.
- March 12, 2024: Effective June 1, 2024, clarified that coverage of a non-formulary drug is determined using documentation that the patient has had a treatment failure of two (2) or more formulary alternative medications within the same therapeutic class (where coverage is listed on the formulary as applicable).
- October 8, 2024: Effective January 1, 2025, for formularies subject to non-formulary review, added non-formulary coverage criteria for Wegovy's supplemental indication for secondary cardiovascular prevention in overweight/obesity.
- February 11, 2025: Effective May 1, 2025, for formularies subject to non-formulary review, added coverage criteria for Zepbound's supplemental indication for moderate to severe obstructive sleep apnea in obesity.
- March 11, 2025: Effective May 1, 2025, administrative clarification to the non-formulary coverage criteria for Zepbound's supplemental indication for moderate to severe obstructive sleep apnea in obesity to indicate use of the AASM 1B hypopnea scoring method.

  Effective July 1, 2025, added clarification about documentation of needle phobia when requesting injectable products. Added clarification on adequate trial of preferred weight loss medications for applicable formularies. Added clarification for formulary alternatives as appropriate for member's age.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other

government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.