Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Non-Formulary Exceptions**

Effective: August 1, 2026

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

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 either New To Market (NTM) and have not yet been reviewed Point32Health's Pharmacy and Therapeutics Committee for safety and clinical effectiveness and made the determination to cover it, or are determined as non-formulary and 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 authorize a formulary exception of a new-to-market medication when **ALL** of the following criteria are met:

New-to-Market

1. The request for coverage is for a newly FDA-approved drug for a use that is covered in the Member's benefit document.

AND

2. Documentation or one (1) of the following for an exception:
    a. The patient is suffering from a health condition that may seriously jeopardize their life, health or ability to regain maximum function

The plan may authorize 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 1.25%), Qlosi (pilocarpine HCl 0.4%), Vizz (aceclidine 1.44%), Yuvezzi (carbachol 2.75% and brimonidine 0.1%)

Initial Authorization

The plan may authorize coverage of **Vuity (pilocarpine 1.25%)**, **Qlosi (pilocarpine 0.4%), Vizz (aceclidine 1.44%), Yuvezzi (carbachol 2.75% and brimonidine 0.1%)** 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. One of the following:
   a. For Vuity, the patient is 40 years of age or older
   b. For Qlosi, Vizz, and Yuvezzi, the patient is 45 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

Tryngolza (olezarsen)

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

Familial Chylomicronemia Syndrome (FCS):

Initial Authorization

1. The patient is 18 years of age or older

AND

2. Documented diagnosis of familial chylomicronemia syndrome (FCS)

AND

3. The patient has a fasting triglyceride level greater than or equal to 880mg/dl at baseline prior to treatment with a triglyceride-lowering medication

AND

4. Documentation the patient will be using Tryngolza (olezarsen) in combination with a very low-fat diet (less than 20gm per day of fat)

AND

5. Documentation Tryngolza will be prescribed by a cardiologist, an endocrinologist, lipidologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia

Reauthorization

1. Documented diagnosis of familial chylomicronemia syndrome (FCS)

AND

2. Documentation that the member has received a 30-50% reduction in the baseline fasting triglyceride level since using Tryngolza (olezarsen) therapy

AND

3. Documentation the patient is using Tryngolza (olezarsen) in combination with a very low-fat diet (less than 20 gm per day of fat)

Severe hypertriglyceridemia (sHTG):

Initial Authorization

1. The patient is 18 years of age or older

AND

2. Documented diagnosis of severe hypertriglyceridemia (sHTG)

AND

3. The patient has had at least two fasting triglyceride levels greater than or equal to 500mg/dl

AND

4. Documentation the patient will continue using lipid-lowering therapies in addition to Tryngolza (olezarsen) such as a high to moderate intensity statin, fibrate, or prescription strength omega-3 fatty acid

AND

5. Documentation the patient will be using Tryngolza (olezarsen) as an adjunct to diet to reduce triglycerides and the risk of acute pancreatitis

AND

6. Documentation Tryngolza (olezarsen) will be prescribed by a cardiologist, an endocrinologist, lipidologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia

Reauthorization

1. Documented diagnosis of severe hypertriglyceridemia (sHTG)

AND

2. Documentation that the patient has had at least a 30-50% reduction in the baseline triglyceride level since using Tryngolza (olezarsen) therapy

AND

3. Documentation the patient will continue using lipid-lowering therapies in addition to Tryngolza (olezarsen) such as a high to moderate intensity statin, fibrate, or prescription strength omega-3 fatty acid

AND

4. Documentation the patient is using Tryngolza (olezarsen) as an adjunct to diet to reduce triglycerides and the risk of acute pancreatitis

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) injection and tablet for Secondary Cardiovascular Prevention in Overweight or Obesity

Initial Authorization:

For Value/Premium formularies subject to non-formulary review, the plan may authorize coverage of **Wegovy (semaglutide) injection/tablet** 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 1 or 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. One of the following:
    a. For the injection, member is currently on a maintenance dose of 1.7 mg or 2.4 mg once weekly
    b. For the tablet, member is currently on a maintenance dose of 25 mg once daily

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 1 or type 2 diabetes
    b. New York Heart Association (NYHA) class IV heart failure

Wegovy (semaglutide) injection for Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis

Initial Authorization:

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

1. Patient is 18 years of age or older

AND

2. Submission of chart note or medical record confirming diagnosis of noncirrhotic, non-alcoholic steatohepatitis (or metabolic dysfunction-associated steatohepatitis) (NASH/MASH)

AND

3. Submission of chart note or medical record confirming fibrosis stage F2 or F3 as confirmed by one of the following:
    a. Both of the following:
        i. Fibrosis 4 index (FIB-4) score greater than or equal to 1.3
        ii. One of the following:
            1. Enhanced liver fibrosis (ELF) test
            2. Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan)
    b. One of the following:
        i. FibroScan aspartate aminotransferase (FAST)
        ii. MRI aspartate aminotransferase (MAST)
        iii. Magnetic Resonance Elastography combined with fibrosis-4 index (MEFIB)
        iv. Liver biopsy within the past 12 months

AND

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

AND

5. Alcohol consumption of no more than 20 g per day for women and no more than 30 g per day for men

AND

6. Prescribed by a gastroenterologist or hepatologist

AND

7. Patient does not have documentation for any of the following:
    a. Presence or history of human immunodeficiency virus (HIV) infection or chronic liver disease other than non-alcoholic fatty liver disease (NAFLD). This includes no known presence of hepatitis C virus (HCV) RNA within 2 years of screening and no known presence of hepatitis B at any timepoint.
    b. Estimated glomerular filtration rate of less than 30 mL/min/1.73 m^2
    c. Type 1 diabetes
    d. New York Heart Association (NYHA) class IV heart failure

Reauthorization Criteria:

First Reauthorization:

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

AND

2. One of the following:
    a. Patient is currently on a maintenance dose of 2.4 mg once weekly
    b. Patient is currently on 1.7 mg once weekly if maintenance dose of 2.4 mg once weekly is not tolerated

AND

3. Documentation by the prescribing physician that the patient is adherent to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

4. Alcohol consumption of no more than 20 g per day for women and no more than 30 g per day for men

AND

5. Prescribed by or in consultation with a gastroenterologist or hepatologist

AND

6. Patient does not have documentation for any of the following:
    a. Progression to cirrhosis
    b. Presence or history of human immunodeficiency virus (HIV) infection or chronic liver disease other than non-alcoholic fatty liver disease (NAFLD). This includes no known presence of hepatitis C virus (HCV) RNA within 2 years of screening and no known presence of hepatitis B at any timepoint
    c. Estimated glomerular filtration rate of less than 30 mL/min/1.73 m^2
    d. Type 1 diabetes
    e. New York Heart Association (NYHA) class IV heart failure

Subsequent Reauthorizations:

1. Patient demonstrates positive response to therapy, as documented by MASH resolution, fibrosis stage improvement, or no worsening of fibrosis as confirmed by liver biopsy or elastography

AND

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

AND

3. One of the following:
    a. Patient is currently on a maintenance dose of 2.4 mg once weekly
    b. Patient is currently on 1.7 mg once weekly if maintenance dose of 2.4 mg once weekly is not tolerated

AND

4. Documentation by the prescribing physician that the patient is adherent to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

AND

5. Alcohol consumption of no more than 20 g per day for women and no more than 30 g per day for men

AND

6. Prescribed by or in consultation with a gastroenterologist or hepatologist

AND

7. Patient does not have documentation for any of the following:
    a. Progression to cirrhosis
    b. Presence or history of human immunodeficiency virus (HIV) infection or chronic liver disease other than non-alcoholic fatty liver disease (NAFLD). This includes no known presence of hepatitis C virus (HCV) RNA within 2 years of screening and no known presence of hepatitis B at any timepoint
    c. Type 1 diabetes
    d. Estimated glomerular filtration rate of less than 30 mL/min/1.73 m^2
    e. New York Heart Association (NYHA) class IV heart failure

Limitations

1. Duration of coverage will be based on the following:
    - Formulary exceptions for new-to-market exclusions will be limited to 12 months, or up to a complete course of therapy if less than one year as noted in the medication's FDA-approved package insert, or as deemed clinically necessary by the plan, and as may be outlined in existing clinical coverage class medical necessity guidelines.
    - 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, Qlosi, Vizz, and Yuvezzi will be authorized for 12 months.
    - Formulary exceptions for Tryngolza will be authorized for an initial duration of six (6) months and twelve (12) months upon reauthorization.
    - For Value/Premium formularies, the plan will only authorize non-formulary coverage of Wegovy injection/tablet for secondary cardiovascular prevention in overweight/obesity or Wegovy injection for metabolic dysfunction-associated steatohepatitis (MASH). The plan will not authorize Wegovy for indications not listed with drug-specific non-formulary coverage criteria.
        - Formulary exceptions for Wegovy injection/tablet 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 Wegovy injection for metabolic dysfunction-associated steatohepatitis (MASH) will be authorized for an initial duration of six (6) months, first reauthorization for up to six (6) months, and subsequent reauthorization for up to twelve (12) months.
    - Formulary exceptions for initial authorization of Wegovy injection or Saxenda for weight loss in pediatric members less than 18 years of age will be for 6 months or until the 18th birthday, whichever is sooner
    - Formulary exceptions for reauthorization of Wegovy injection or Saxenda for weight loss in pediatric members less than 18 years of age will be for 12 months or until the 18th birthday, whichever is sooner
    - 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. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria.
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. 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.
6. 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.
7. Documentation of a patient having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.
8. 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.
9. 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.
10. 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. Abilify MyCite (aripiprazole tablet with sensor) [prescribing information]. Tokyo, Japan: Otsuka Pharmaceuticals; 2021 August.
4. Wegovy (semaglutide) [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S. February 2026.
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11. Vizz (aceclidine) ophthalmic solution [prescribing information]. Solana Beach, CA: LENZ Therapeutics, Inc; August 2025.
12. Tryngolza (olezarsen) injection [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc; June 2026.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- 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 non-formulary 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.
- April 9, 2025: Effective May 1, 2025, added coverage criteria for Qlosi.

  Effective July 1, 2025, updated duration of Wegovy and Saxenda coverage for pediatric members.
- May 13, 2025: Effective August 1, 2025, updated limitation statement to clarify non-formulary coverage of Wegovy and Zepbound for indications listed with drug-specific non-formulary coverage criteria.
- July 8, 2025: Effective October 1, 2025, clarified the initial non-formulary coverage criteria for Zepbound in moderate to severe obstructive sleep apnea in obesity to require submission of chart note or medical record with documentation that the member has not been able to tolerate CPAP despite reasonable attempts to adjust to the CPAP and mask.
- September 9, 2025: Effective September 15, 2025, for formularies subject to non-formulary review, added non-formulary coverage criteria for Wegovy's supplemental indication for noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. Updated non-formulary coverage criteria for Zepbound in moderate to severe obstructive sleep apnea in obesity to require 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 from the past 365 days to the past 2 years.

- September 9, 2025: Effective January 1, 2026, clarified that non-formulary review of Wegovy for secondary cardiovascular prevention in overweight/obesity or metabolic dysfunction-associated steatohepatitis (MASH) is applicable to only Value and Premium formularies. Updated Wegovy's non-formulary criteria for secondary cardiovascular prevention in overweight/obesity to exclude type 1 diabetes. Removed non-formulary coverage criteria for Zepbound in moderate to severe obstructive sleep apnea in obesity.
- January 13, 2026: Effective February 1, 2026, added coverage criteria for Vizz.
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.
- March 10, 2026: Effective May 1, 2026, added clarification that coverage criteria for secondary cardiovascular prevention in overweight/obesity apply to both the Wegovy injection and tablet, and that coverage criteria for metabolic dysfunction-associated steatohepatitis apply to the Wegovy injection. This update was also reflected in the limitation section accordingly. Administrative update to clarify Wegovy injection for pediatric members. Administrative update to the limitation statement to include members initiated on the requested medication by self-paying for the medication directly do not qualify for established clinical response and should be reviewed against initial approval criteria. Effective June 1, 2026, added PA criteria for formulary exceptions to support the exclusion exception process of New-to-market drugs. Removed limitation stating excluded medication will not be reviewed with Non-Formulary Exceptions guideline, and added approval duration for formulary exceptions for new-to-market drugs.
- May 12, 2026: Effective August 1, 2026, added coverage criteria for Yuvezzi and Tryngolza.
- July 14, 2026: Updated coverage criteria for Tryngolza to include new indication of severe hypertriglyceridemia (sHTG).

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.