Clinical Policy: Obesity Treatment Agents

Reference Number: PHW.PDL.750
Effective Date: 01/09/2023
Last Review Date: 11/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Obesity Treatment Agents is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Obesity Treatment Agents

A. <u>Prescriptions That Require Prior Authorization</u>

All prescriptions for Obesity Treatment Agents must be prior authorized.

B. <u>Review of Documentation for Medical Necessity</u>

In evaluating a request for prior authorization of a prescription for an Obesity Treatment Agent, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a request for Evekeo (amphetamine) for any indication other than the treatment of obesity, see PHW.PDL.007 Stimulants and Related Agents; **OR**

2. **One** of the following:

   a. For members 18 years of age and older, **one** of the following:

      i. Has a body mass index (BMI) greater than or equal to 30 kg/m^2

      ii. **Both** of the following:

         a) **One** of the following:

            (i) Has a BMI greater than or equal to 27 kg/m^2 and less than 30 kg/m^2
            (ii) Has been determined by the prescriber to be a candidate for treatment based on degree of adiposity, waist circumference, history of bariatric surgery, BMI exceptions for the member's ethnicity, etc.

         b) Has at least **one** weight-related comorbidity as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc.

b. For members less than 18 years of age, has a BMI in the 95th percentile or greater standardized for age and sex based on current Centers for Disease Control and Prevention (CDC) charts;

AND

3. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**

4. Is age- and weight-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

6. Does not have a contraindication to the prescribed drug; AND

7. For Evekeo (amphetamine), **all** of the following:

   a. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,

   b. Has documentation that the member has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,

   c. For a member with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances,

   d. **Both** of the following:

      i. Has a history of trial and failure of or a contraindication or an intolerance to all other Obesity Treatment Agents (preferred and non-preferred)
      ii. Has documentation from the prescriber explaining the rationale for why the requested drug is needed and a plan for tapering;

   AND

8. For a preferred Obesity Treatment Agent containing a glucagon-like peptide-1 (GLP-1) receptor agonist, **one** of the following:

   a. Has **both** of the following:

i. A diagnosis of diabetes mellitus or a history of an antidiabetic drug in the last 120 days
ii. A history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the Preferred Drug List (PDL).
See the PDL for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist at: https://papdl.com/preferred-drug-list.

b. Does not have a diagnosis of diabetes mellitus or a history of an antidiabetic drug in the last 120 days;

AND

9. For a non-preferred Obesity Treatment Agent containing a GLP-1 receptor agonist, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

a. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis
b. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis

See the PDL for the list of preferred Obesity Treatment Agents and Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist at: https://papdl.com/preferred-drug-list;

AND

10. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the member's diagnosis or indication. See the PDL for the list of preferred Obesity Treatment Agents at: https://papdl.com/preferred-drug-list; AND

11. For therapeutic duplication, **one** of the following:

a. For a drug containing a GLP-1 receptor agonist, is being titrated to or tapered from a dipeptidyl peptidase-4 (DPP-4) inhibitor or another drug containing a GLP-1 receptor agonist,
b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
c. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

12. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR OBESITY TREATMENT AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Obesity Treatment Agent that was previously approved will take into account whether the member:

1. **One** of the following:

   a. Is continuing with dose titration,

   b. **One** of the following:

      i. For members 18 years of age and older, experienced a percent reduction of baseline body weight that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose
      ii. For members less than 18 years of age, experienced a percent reduction of baseline BMI or BMI z-score that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,

   c. Experienced improvement in degree of adiposity or waist circumference from baseline,

   d. Experienced clinical benefit from the Obesity Treatment Agent in at least **one** weight-related comorbidity from baseline as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc;

   AND

2. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Does not have a contraindication to the prescribed drug; AND

5. For Evekeo (amphetamine), both of the following:

   a. For a member with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances
   b. Has documentation from the prescriber explaining the rationale for why the requested drug continues to be needed and plan for tapering;

   AND

6. For a non-preferred Obesity Treatment Agent containing a GLP-1 receptor agonist, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

   a. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis
   b. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis

   See the PDL for the list of preferred Obesity Treatment Agents and Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist at: https://papdl.com/preferred-drug-list;

   AND

7. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the member's diagnosis or indication. See the PDL for the list of preferred Obesity Treatment Agents at: https://papdl.com/preferred-drug-list; AND

8. For therapeutic duplication, **one** of the following:

   a. For a drug containing a GLP-1 receptor agonist, is being titrated to or tapered from a DPP-4 inhibitor or another drug containing a GLP-1 receptor agonist,
   b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
   c. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

9. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Obesity Treatment Agents. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member

C. Dose and Duration of Therapy

Requests for prior authorization of Obesity Treatment Agents will be approved as follows:

1. For Evekeo (amphetamine), all requests will be approved for up to 3 months.

2. For a drug containing a GLP-1 receptor agonist (e.g., Saxenda, Wegovy, or Zepbound), all requests will be approved for up to 6 months.

3. For all other Obesity Treatment Agents:
   a. Initial requests for prior authorization will be approved for up to 4 months.
   b. Renewals of requests for prior authorization will be approved for up to 6 months.

C. References

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GLP-1 RECEPTOR AGONISTS FOR MEMBERS WITH OTHER COVERAGE (NON-MEDICARE TPL OR MEDICARE PART D)	
Member's diagnosis(es)	**Primary payer v. Medical Assistance coverage**
Diabetes	The primary payer should review/pay for a GLP-1 receptor agonist indicated for diabetes.† • Request documentation of denial and appeal from primary insurer.
Obesity/overweight + diabetes	The primary payer should review/pay for a GLP-1 receptor agonist indicated for diabetes.† • Request documentation of denial and appeal from primary insurer.
Obesity/overweight + established CVD*	The primary should review/pay for a GLP-1 receptor agonist indicated for obesity/overweight + established CVD (eg, Wegovy). • Request documentation of denial and appeal from primary insurer.
Obesity/overweight, NO diabetes dx, NO established CVD* dx	Request documentation of denial and appeal from primary insurer or exclusion of obesity treatments from primary insurer's coverage.

†GLP-1 receptor agonists indicated for the treatment of diabetes include Bydureon (exenatide microspheres), Byetta (exenatide), Mounjaro (tirzepatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), Victoza (liraglutide).

*Established CVD (cardiovascular disease) per the SELECT trial refers to at least one of the following:

- Prior myocardial infarction (MI).
- Prior stroke (ischemic or hemorrhagic stroke).
- Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) <0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.

Reviews, Revisions, and Approvals	**Date**
Policy created	10/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024	11/2023
Q2 2024: added criteria for GLP-1 receptor agonist review for members with other coverage	04/2024
Q3 2024: policy revised according to DHS revisions effective 09/02/2024.	07/2024
Q1 2025 annual review: no changes.	11/2024