PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
OBESITY TREATMENT AGENTS

Proposed Effective Date: September 2, 2024

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Obesity Treatment Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Obesity Treatment Agents must be prior authorized.

B. Revisions to Review of Documentation for Medical Necessity

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 beneficiary:

1. For a request for Evekeo (amphetamine) for any indication other than the treatment of obesity, see the prior authorization guidelines related to Stimulants and Related Agents; **OR**

2. **One of the following:**

   a. For beneficiaries 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 beneficiary'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 beneficiaries 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 beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,

   c. For a beneficiary 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 beneficiary's diagnosis**
   b. **The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary'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 beneficiary'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** ~~glucagon-like peptide-1 (~~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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

    NOTE: If the beneficiary 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 beneficiary, 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 beneficiary:

1. **One of the following:**

   a. Is continuing with dose titration,

   b. **One of the following:**

      i. For beneficiaries 18 years of age and older, ~~**one** of the following:~~ 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 beneficiaries less than 18 years of age, ~~**one** of the following:~~ 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. ~~Continues to experience~~ **Experienced** clinical benefit from the Obesity Treatment Agent **in at least one weight-related comorbidity from baseline** ~~based on the prescriber's assessment~~ **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 beneficiary 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 beneficiary's diagnosis**
   b. **The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary'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 beneficiary'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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   NOTE: If the beneficiary 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 beneficiary, 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 an Obesity Treatment Agent. 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 beneficiary.

C. Revisions to 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**,** ~~or~~ 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.

D. References

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