Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
August 7, 2024	September 2, 2024	*See below

SUBJECT

Prior Authorization of Obesity Treatment Agents – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Obesity Treatment Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Obesity Treatment Agents will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Obesity Treatment Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

*01-24-12	09-24-12	27-24-09	33-24-12
02-24-08	11-24-07	30-24-07	
03-24-07	14-24-08	31-24-13	
08-24-13	24-24-10	32-24-07	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html.

During the June 12, 2024, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of Obesity Treatment Agents:

- Updated language referring to "glucagon-like peptide-1 (GLP-1) receptor agonist" throughout the guidelines to "drug containing a GLP-1 receptor agonist" to account for newer combination drugs in the class and any new combination drugs to market that include a GLP-1 receptor agonist in addition to one or more active ingredients with a different mechanism of action.
- Addition of "cardiovascular disease" to the list of examples of weight-related comorbidities.
- Addition of a guideline for initial requests for a preferred Obesity Treatment Agent containing a GLP-1 receptor agonist that for beneficiaries with a diagnosis of diabetes mellitus or a history of an antidiabetic drug in the last 120 days, the beneficiary has 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).
- Addition of a guideline for initial and renewal requests of a non-preferred Obesity Treatment Agent containing a GLP-1 receptor agonist that the beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to both the preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis and the preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis.
- Revision to the renewal guidelines to include additional options that the beneficiary has experienced improvement in degree of adiposity or waist circumference from baseline or 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.

The revisions to the guidelines to determine medical necessity of prescriptions for Obesity Treatment Agents submitted for prior authorization, as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Obesity Treatment Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Obesity Treatment Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

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. 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 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, 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, 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 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. 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.

D. References

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