pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 14, 2023	January 8, 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.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

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) Pharmacy and Therapeutics (P&T)

*01-23-49	09-23-48	27-23-39	33-23-46
02-23-37	11-23-37	30-23-40	
03-23-35	14-23-36	31-23-50	
08-23-52	24-23-45	32-23-35	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).
- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 13, 2023, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Obesity Treatment Agents:

- Deletion of the guidelines for beneficiaries less than 18 years of age who do not have a body mass index in the 95th percentile or greater.
- Deletion of the guidelines related to documentation that the prescriber or prescriber's delegate conducted a search of the Prescription Drug Monitoring Program.
- Revision of the renewal guidelines for all beneficiaries to clarify that a response to therapy will not be evaluated for beneficiaries who are continuing with dose titration.

The revisions to the guidelines to determine medical necessity of prescriptions for Obesity Treatment Agents submitted for prior authorization, as recommended by the P&T Committee, 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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

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

    b. **Both** of the following:

        i. **One** of the following:

            a) Has a BMI greater than or equal to 27 kg/m^2 and less than 30 kg/m^2
            b) 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.

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

    AND

3. 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**

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

5. Is age- and weight-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

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

7. Does not have a contraindication to the prescribed medication; **AND**

8. 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 medication is needed and a plan for tapering;

   AND

9. 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 Preferred Drug List (PDL) for the list of preferred Obesity Treatment Agents at: https://papdl.com/preferred-drug-list; **AND**

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

    a. For 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 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 medications that is supported by peer-reviewed medical literature or national treatment guidelines;

    AND

11. 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

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

   a. Is continuing with dose titration,
   b. 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,
   c. Continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment;

   AND

2. For beneficiaries less than 18 years of age, **one** of the following:

   a. Is continuing with dose titration,
   b. 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. Continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment;

   AND

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

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

5. Does not have a contraindication to the prescribed medication; **AND**

6. 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 medication continues to be needed and plan for tapering;

   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 GLP-1 receptor agonist, is being titrated to or tapered from a DPP-4 inhibitor or another 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 medications 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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.

C. 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.

D. 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 GLP-1 receptor agonist (e.g., Saxenda or Wegovy), 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.

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