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 Hypoglycemics, Incretin Mimetics/Enhancers – Pharmacy Services

BY

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Office of Medical Assistance Programs

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 Hypoglycemics, Incretin Mimetics/Enhancers 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 Hypoglycemics, Incretin Mimetics/Enhancers 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 Hypoglycemics, Incretin Mimetics/Enhancers 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.

*01-24-11	09-24-11	27-24-08	33-24-11
02-24-07	11-24-06	30-24-06	
03-24-06	14-24-07	31-24-12	
08-24-12	24-24-09	32-24-06	

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.

DISCUSSION:

During the June 12, 2024, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers:

- Revision of 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 a requirement for prior authorization of prescriptions for preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist.
- Addition of medical necessity guidelines for Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist for the treatment of diabetes.
- Revision of language referring to "the treatment of obesity" throughout the guidelines to "the treatment of overweight or obesity" to more accurately reflect that the corresponding guidelines in the document apply to both beneficiaries with a diagnosis of overweight and beneficiaries with a diagnosis of obesity.
- Addition of "cardiovascular disease" to the list of examples of weight-related comorbidities.
- Revision of the guideline for non-preferred drugs containing a GLP-1 receptor agonist for the treatment of overweight or obesity to consider a history of therapeutic failure of or a contraindication or an intolerance to both the preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the Preferred Drug List (PDL) medically accepted for the beneficiary's diagnosis and the preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis.
- Revision to the renewal guidelines for the determination of medical necessity of a request for renewal of a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist for a diagnosis of overweight or obesity 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 drug containing a GLP-1 receptor agonist 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 Hypoglycemics, Incretin Mimetics/Enhancers 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 Hypoglycemics, Incretin Mimetics/Enhancers 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 Hypoglycemics, Incretin Mimetics/Enhancers) 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 Hypoglycemics, Incretin Mimetics/Enhancers

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemics, Incretin Mimetic/Enhancer. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemics, Incretin Mimetic/Enhancer with a prescribed quantity that exceeds the quantity limit. 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.

3. A Hypoglycemics, Incretin Mimetic/Enhancer containing a glucagon-like peptide-1 (GLP-1) receptor agonist.

4. A drug containing a GLP-1 receptor agonist when there is a record of a recent paid claim for another drug containing a GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the point-of-sale online claims adjudication system (therapeutic duplication).

5. A DPP-4 inhibitor when there is a record of a recent paid claim for another DPP-4 inhibitor or a drug containing a GLP-1 receptor agonist in the point-of-sale online claims adjudication system (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, **both** of the following:

   a. **One** of the following:

      i. For the treatment of diabetes, has at least **one** of the following:

         a) A diagnosis of diabetes mellitus
         b) A history of an antidiabetic drug (excluding drugs containing a GLP-1 receptor agonist) within the last 120 days

      ii. For the treatment of overweight or obesity, **all** of the following:

a) **One** of the following:

(i) 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, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc.

(ii) 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 charts,

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

c) 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,

d) Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

e) Does not have a contraindication to the prescribed drug

b. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, **one** of the following:

i. For the treatment of overweight or obesity, has history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

a) The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis

b) The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis

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

ii. For the treatment of all other diagnoses, 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 approved or medically accepted for the beneficiary's diagnosis;

AND

2. For all other non-preferred Hypoglycemics, Incretin Mimetics/Enhancers, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers with the same mechanism of action approved or medically accepted for the beneficiary's diagnosis; **AND**

3. For therapeutic duplication of a drug containing a GLP-1 receptor agonist or a DPP-4 inhibitor, **one** of the following:

   a. Is being transitioned to or from another drug containing a GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the drugs
   b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

4. If a prescription for a Hypoglycemics, Incretin Mimetics/Enhancers 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.

   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 A HYPOGLYCEMICS, INCRETIN MIMETIC/ENHANCER CONTAINING A GLP-1 RECEPTOR AGONIST FOR A DIAGNOSIS OF OVERWEIGHT OR OBESITY: The determination of medical necessity of a request for renewal of a prior authorization for a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist for a diagnosis of overweight or obesity 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 drug containing a GLP-1 receptor agonist 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 a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, has history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

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

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

AND

6. For therapeutic duplication of a drug containing a GLP-1 receptor agonist, **one** of the following:

   a. Is being transitioned to or from another drug containing a GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the drugs
   b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

7. If a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer 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.

   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 a Hypoglycemics, Incretin Mimetic/Enhancer. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable 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

1. For a diagnosis of overweight or obesity, all requests will be approved for up to 6 months.