


ISSUE DATE November 13, 2023	EFFECTIVE DATE January 8, 2023	NUMBER *See below
SUBJECT Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary 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.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 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:

*01-23-42	09-23-41	27-23-32	33-23-39
02-23-30	11-23-30	30-23-33	
03-23-28	14-23-29	31-23-43	
08-23-45	24-23-38	32-23-28	

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>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) 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 reviewed revisions to the medical necessity guidelines for Hypoglycemics, Incretin Mimetics/Enhancers to include guidelines for requests for non-preferred glucagon-like peptide-1 receptor agonists for the treatment of obesity.

The revisions to the guidelines to determine medical necessity of prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers submitted for prior authorization 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.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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 Hypoglycemic, Incretin Mimetic/Enhancer. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetic/Enhancers at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A glucagon-like peptide-1 (GLP-1) receptor agonist when there is a record of a recent paid claim for another GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. A DPP-4 inhibitor when there is a record of a recent paid claim for another DPP-4 inhibitor or 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 Hypoglycemic, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Incretin Mimetic/Enhancer GLP-1 receptor agonist, **one** of the following:
 - a. For a diagnosis of obesity, **all** 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/m²
 - b) **Both** of the following:
 - (i) **One** of the following:
 - a. Has a BMI greater than or equal to 27 kg/m² and less than 30 kg/m²

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- 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.,
- 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,
- iii. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity),
- iv. Is age- and weight-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- v. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- vi. Does not have a contraindication to the prescribed medication,
- vii. Has history of therapeutic failure of or a contraindication or an intolerance to the preferred GLP-1 receptor agonists on the Statewide PDL approved or medically accepted for the beneficiary's diagnosis or indication
- b. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemic, Incretin Mimetic/Enhancer GLP-1 receptor agonists 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 GLP-1 receptor agonist or a DPP-4 inhibitor, **one** of the following:
 - a. Is being transitioned to or from another GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

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4. If a prescription for a Hypoglycemic, 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.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A NON-PREFERRED HYPOGLYCEMIC, INCRETIN MIMETIC/ENHANCER GLP-1 RECEPTOR AGONIST FOR A DIAGNOSIS OF OBESITY: The determination of medical necessity of a request for renewal of a prior authorization for a non-preferred Hypoglycemic, Incretin Mimetic/Enhancer GLP-1 receptor agonist for a diagnosis of obesity 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 GLP-1 receptor agonist 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 GLP-1 receptor agonist 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**

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5. Does not have a contraindication to the prescribed medication; **AND**
6. Has history of therapeutic failure of or a contraindication or an intolerance to the preferred GLP-1 receptor agonists on the Statewide PDL approved or medically accepted for the beneficiary's diagnosis or indication; **AND**
7. For therapeutic duplication of a GLP-1 receptor agonist, one of the following:
 - a. Is being transitioned to or from another GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

8. If a prescription for a Hypoglycemic, 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 Hypoglycemic, 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 obesity, all requests will be approved for up to 6 months.