


<b>ISSUE DATE</b>  November 10, 2020	<b>EFFECTIVE DATE</b>  January 5, 2021	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers – Pharmacy Services		<b>BY</b>   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 delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Hypoglycemics, Incretin Mimetics/Enhancers to the appropriate managed care organization.

*01-20-29	09-20-28	27-20-24	33-20-25
02-20-22	11-20-22	30-20-21	
03-20-22	14-20-23	31-20-29	
08-20-32	24-20-22	32-20-21	

**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>.

**BACKGROUND:**

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

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

**DISCUSSION:**

During the August 11, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Hypoglycemics, Incretin Mimetics/Enhancers:

- Addition of a guideline that treatment of the beneficiary's diagnosis with the requested Incretin Mimetic/Enhancer is consistent with FDA-approved package labeling or medical literature;
- Addition of a guideline for beneficiaries who require initial dual therapy with metformin and another hypoglycemic medication based on recent consensus treatment guideline recommendations;
- Addition of a guideline for beneficiaries who have heart failure, chronic kidney disease, cardiovascular disease, or two or more risk factors for cardiovascular disease based on recent consensus treatment guideline recommendations; and
- Addition of a guideline for prescriptions for an Incretin Mimetic/Enhancer that may represent a therapeutic duplication.

The revisions to the guidelines to determine medical necessity of Hypoglycemics, Incretin Mimetics/Enhancers, 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 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 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**

All prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers must be prior authorized.

**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. Is prescribed the Hypoglycemic, Incretin Mimetic/Enhancer for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding use to treat obesity; **AND**
2. For a glucagon-like peptide-1 (GLP-1) receptor agonist or dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, has a documented history of **one** of the following:
  - a. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin,
  - b. A contraindication or intolerance to metformin,
  - c. Requires initial dual therapy with metformin based on HbA1c as defined by the American Diabetes Association or the American Association of Clinical Endocrinologists and American College of Endocrinology,
  - d. For a GLP-1 receptor agonist or DPP-4 inhibitor with proven cardiovascular disease (CVD), heart failure (HF), or chronic kidney disease (CKD) benefit, has CVD (or two risk factors for CVD as identified by the American Diabetes Association or the American Association of Clinical Endocrinologists and American College of Endocrinology), HF, or CKD;

**AND**

3. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer, has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Hypoglycemics, Incretin Mimetics/Enhancers with the same mechanism of action. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers at: <https://papdl.com/preferred-drug-list>; **AND**
4. For an amylin analog, **all** of the following:

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- a. For a diagnosis of type 2 diabetes mellitus, has a documented history of **one** of the following:
  - i. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin
  - ii. A contraindication or intolerance to metformin,
- b. Failed to achieve adequate glycemic control as evidenced by the beneficiary's HbA1c values despite compliance with optimal insulin therapy,
- c. Will be prescribed the requested amylin analog in combination with insulin;

**AND**

5. For therapeutic duplication, **one** of the following:
  - a. Is being transitioned to or from another Hypoglycemics, Incretin Mimetic/Enhancer 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 literature or national treatment guidelines;

**AND**

6. 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. 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 PRESCRIPTIONS FOR AN AMYLIN ANALOG: Requests for prior authorization of renewals of prescriptions for an amylin analog that were previously approved will take into account whether the beneficiary:

1. Has improved glycemic control as evidenced by a recent HbA1c value; **AND**
2. For therapeutic duplication, **one** of the following:

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- a. Is being transitioned to or from another Hypoglycemics, Incretin Mimetic/Enhancer 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 literature or national treatment guidelines;

**AND**

3. If a prescription for an amylin analog 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 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. Automated Prior Authorization

Prior authorization of a prescription for a preferred Hypoglycemics, Incretin Mimetic/Enhancer (except for an amylin analog) with a prescribed quantity that does not exceed the quantity limit will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 90 days of the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

E. References

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1. American Diabetes Association. Pharmacologic approaches to glycemic treatment. Sec. 9. In Standards of Medical Care in Diabetes – 2020. Diabetes Care 2020 Jan; 43 (Supplement 1): S98-S110. <https://doi.org/10.2337/dc20-S009>
2. American Diabetes Association. Cardiovascular disease and risk management. Sec. 10. In Standards of Medical Care in Diabetes – 2020. 020 Jan; 43 (Supplement 1): S98-S110. <https://doi.org/10.2337/dc20-S009>
3. Garber AJ, Handelsman Y, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2020 executive summary. Endocrine Practice. 2020;26(1):107-139.
4. Symlin prescribing information. AstraZeneca Pharmaceuticals. LP Wilmington, DE. 2015