pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 10, 2022	January 9, 2023	*See below

SUBJECT

Prior Authorization of Hypoglycemics, Insulin and Related Agents – 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.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, Insulin and Related 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 Hypoglycemics, Insulin and Related 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 Hypoglycemics, Insulin and Related Agents to the appropriate managed care organization.

BACKGROUND:

*01-22-64	09-22-63	27-22-51	33-22-61
02-22-48	11-22-48	30-22-54	
03-22-47	14-22-48	31-22-67	
08-22-72	24-22-56	32-22-48	

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

DISCUSSION:

During the September 14, 2022, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Hypoglycemics, Insulin and Related Agents:

- Removal of the requirement for prior authorization of preferred Hypoglycemics, Insulin and Related Agents combination agents that contain a glucagon-like peptide-1 (GLP-1) receptor agonist that are prescribed for a quantity that does not exceed the quantity limit and do not represent a therapeutic duplication.
- Addition of a requirement for prior authorization and corresponding guidelines for the determination of medical necessity of a GLP-1 receptor agonist that represents a therapeutic duplication.
- Revision of the guidelines for non-preferred Hypoglycemics, Insulin and Related Agents that do not contain a GLP-1 receptor agonist to consider the duration of action of the requested medication.
- Revision of the guidelines for initial requests for prior authorization of non-preferred Hypoglycemics, Insulin and Related Agents combination agents that contain a GLP-1 receptor agonist.
- Removal of the guidelines for requests for renewal of a prior authorization for Hypoglycemics, Insulin and Related Agents combination agents that contain a GLP-1 receptor agonist.
- Revision of the guidelines for Afrezza (insulin human inhalation powder).

The revisions to the guidelines to determine medical necessity of prescriptions for Hypoglycemics, Insulin and Related 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 Hypoglycemics, Insulin and Related 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 Hypoglycemics, Insulin and Related 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 Hypoglycemics, Insulin and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Insulin and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Insulin and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Insulin and Related Agents at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, Insulin and Related Agent combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist 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 On-Line 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, Insulin and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist, **both** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Insulin and Related Agents with the same duration of action
   b. Has a history of contraindication or intolerance to the preferred Hypoglycemics, Insulin and Related Agents that would not be expected to occur with the requested medication;

   AND

2. For a non-preferred Hypoglycemic, Insulin and Related Agent that contains a GLP-1 receptor agonist, **both** of the following:

   a. Has a clinical reason why a preferred basal insulin and a preferred GLP-1 receptor agonist cannot be used
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Insulin and Related Agents that contain a GLP-1 receptor agonist;

AND

3. For Afrezza (insulin human inhalation powder), **all** of the following:

   a. Is prescribed Afrezza (insulin human inhalation powder) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,

   b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

   c. Is prescribed Afrezza (insulin human inhalation powder) by or in consultation with an endocrinologist,

   d. Does not have a contraindication to the prescribed medication;

   AND

4. 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

5. If a prescription for a Hypoglycemic, Insulin and Related Agent combination agent that contains a GLP-1 receptor agonist 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 AFREZZA (insulin human inhalation powder): The determination of medical necessity of a request for renewal of a prior authorization for Afrezza (insulin human inhalation powder) that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the medication as documented by a decrease in hemoglobin A1c; **AND**

2. Is prescribed Afrezza (insulin human inhalation powder) by or in consultation with an endocrinologist; **AND**

3. Does not have a contraindication to the prescribed medication.

   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, Insulin and Related 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. References

1. Afrezza (human insulin) package insert. Danbury, CT: MannKind Corporation; February 2020.