Clinical Policy: Hypoglycemics, Insulin and Related Agents

Reference Number: PHW.PDL.029
Effective Date: 01/01/2020
Last Review Date: 11/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Insulin and Related Hypoglycemic Agents are **medically necessary** when the following criteria are met:

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 Hypoglycemics, Insulin and Related Agent..

2. A Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist with a prescribed quantity that exceeds the quantity limit.

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 (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemics, Insulin and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a non-preferred Hypoglycemics, 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 Hypoglycemics, Insulin and Related Agents 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 contraindications 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 discontinuation 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;

5. If a prescription for a Hypoglycemics, Insulin and Related Agents combination agent that contains a GLP-1 receptor agonist is in 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 PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 of renewals for Afrezza (insulin human inhalation powder) that was previously approved will take into account whether the member:

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

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

c. Does not have a contraindications to the prescribed medication.

NOTE: If the member 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 member, 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, 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 member.

D. **Approval duration: 12 months**

E. References

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

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025 annual review: no changes.	11/2024