Clinical Policy: Hypoglycemics, Incretin Mimetics/Enhancers

Reference Number: PHW.PDL.111
Effective Date: 01/01/2020
Last Review Date: 11/2023

Revision Log

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 Incretin Mimetic/Enhancer Hypoglycemis are **medically necessary** when the following criteria are met:

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.

2. A Hypoglycemic, Incretin Mimetic/Enhancer 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).

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 (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 member:

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/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 member'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 member'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 member'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 member'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

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 PA.CP.PMN.59 Quantity Limit Overrides.

   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 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 member:

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**

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 member'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 PA.CP.PMN.59 Quantity Limit Overrides.

   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, 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 member.

D. <u>Approval Duration</u>: For a diagnosis of obesity, all requests will be approved for up to 6 months

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020
Q1 2023: policy revised according to DHS revisions effective 01/09/2023	10/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024	11/2023