# Clinical Policy: Hypoglycemics, Incretin Mimetics/Enhancers

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**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 Hypoglycemics, Incretin Mimetic/Enhancer containing a glucagon-like peptide-1 (GLP-1) receptor agonist.

4. A drug containing a GLP-1 receptor agonist when there is a record of a recent paid claim for another drug containing a GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the point-of-sale online claims adjudication system (therapeutic duplication).

5. A DPP-4 inhibitor when there is a record of a recent paid claim for another DPP-4 inhibitor or a drug containing 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 Hypoglycemics, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, **both** of the following:

   a. **One** of the following:

i For the treatment of diabetes, has at least **one** of the following:

a. A diagnosis of diabetes mellitus
b. A history of an antidiabetic drug (excluding drugs containing a GLP-1 receptor agonist) within the last 120 days

ii For the treatment of overweight or obesity, **all** of the following:

a. **One** of the following:

i. For members 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, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc.

ii. For members less than 18 years of age, has a BMI in the $95^{th}$ percentile or greater standardized for age and sex based on current Centers for Disease Control and Prevention charts,

b. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity),

c. Is age- and weight-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

d. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

e. Does not have a contraindication to the prescribed drug

b. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, **one** of the following:

i For the treatment of overweight or obesity, has history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

a. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis
b. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis

ii For the treatment of all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist 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 drug containing a GLP-1 receptor agonist or a DPP-4 inhibitor, **one** of the following:

a. Is being transitioned to or from another drug containing a GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the drugs
b. Has a medical reason for concomitant use of the requested drugs 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 HYPOGLYCEMICS, INCRETIN MIMETIC/ENHANCER CONTAINING A GLP-1 RECEPTOR AGONIST FOR A DIAGNOSIS OF OVERWEIGHT OR OBESITY: The determination of medical necessity of a request for renewal of a prior authorization for a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist for a diagnosis of overweight or obesity that was previously approved will take into account whether the member:

1. **One** of the following:

    a. Is continuing with dose titration,

    b. **One** of the following:

        i. For members 18 years of age and older, 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
        ii. For members less than 18 years of age, 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. Experienced improvement in degree of adiposity or waist circumference from baseline,

    d. Experienced clinical benefit from the drug containing a GLP-1 receptor agonist in at least one weight-related comorbidity from baseline as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc;

    **AND**

2. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed drug; **AND**

5. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, has history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

a. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis
b. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the member's diagnosis

**AND**

6. For therapeutic duplication of a drug containing a GLP-1 receptor agonist, **one** of the following:

   a. Is being transitioned to or from another drug containing a GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the drugs
   b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

   **AND**

7. 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. **Approval Duration: For a diagnosis of overweight or obesity, all requests will be approved for up to 6 months**

| GLP-1 RECEPTOR AGONISTS FOR MEMBERS WITH OTHER COVERAGE (NON-MEDICARE TPL OR MEDICARE PART D) | |
|---|---|
| **Member's diagnosis(es)** | **Primary payer v. Medical Assistance coverage** |
| Diabetes | The primary payer should review/pay for a GLP-1 receptor agonist indicated for diabetes.†<br>• Request documentation of denial and appeal from primary insurer. |
| Obesity/overweight + diabetes | The primary payer should review/pay for a GLP-1 receptor agonist indicated for diabetes.†<br>• Request documentation of denial and appeal from primary insurer. |
| Obesity/overweight + established CVD* | The primary should review/pay for a GLP-1 receptor agonist indicated for obesity/overweight + established CVD (eg, Wegovy).<br>• Request documentation of denial and appeal from primary insurer. |
| Obesity/overweight, NO diabetes dx, NO established CVD* dx | Request documentation of denial and appeal from primary insurer or exclusion of obesity treatments from primary insurer's coverage. |

†GLP-1 receptor agonists indicated for the treatment of diabetes include Bydureon (exenatide microspheres), Byetta (exenatide), Mounjaro (tirzepatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), Victoza (liraglutide).

*Established CVD (cardiovascular disease) per the SELECT trial refers to at least one of the following:

- Prior myocardial infarction (MI).
- Prior stroke (ischemic or hemorrhagic stroke).
- Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) <0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.

| 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 |
| Q2 2024: added criteria for GLP-1 receptor agonist review for members with other coverage | 04/2024 |
| Q3 2024: policy revised according to DHS revisions effective 09/02/2024 | 07/2024 |
| Q1 2025 annual review: no changes. | 11/2024 |