PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
HYPOGLYCEMICS, INCRETIN MIMETICS/ENHANCERS

Proposed Effective Date: September 2, 2024

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers

A. Revisions to 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 Hypoglycemics, Incretin Mimetic/Enhancer. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemics, Incretin Mimetic/Enhancer 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

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. Revisions to 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. ~~For a non-preferred Hypoglycemic, Incretin Mimetic/Enhancer GLP-1 receptor agonist, **one** of the following:~~

2. **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 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 beneficiary'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 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,

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

~~f) 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 beneficiary's diagnosis or indication~~

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 beneficiary's diagnosis**
b) **The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis**

See the PDL for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers and Obesity Treatment Agents containing a GLP-1 receptor agonist at: https://papdl.com/preferred-drug-list.

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~~s~~ approved or medically accepted for the beneficiary's diagnosis;

AND

3. 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 beneficiary's diagnosis; **AND**

4. 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

5. If a prescription for a Hypoglycemics, Incretin Mimetics/Enhancers 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 A ~~NON-PREFERRED~~ 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 ~~non-preferred~~ 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 beneficiary:

1. **One of the following:**

   a. Is continuing with dose titration,

   b. **One of the following:**

      i. For beneficiaries 18 years of age and older, ~~**one** of the following:~~ 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 beneficiaries less than 18 years of age, ~~**one** of the following:~~ 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. ~~Continues to experience~~ **Experienced** clinical benefit from the **drug containing a** GLP-1 receptor agonist **in at least one weight-related comorbidity from baseline** ~~based on the prescriber's assessment~~ **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:** ~~has history of therapeutic failure of or a contraindication or an intolerance to the preferred GLP-1 receptor agonist on the PDL approved or medically accepted for the beneficiary's diagnosis or indication;~~

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

   See the PDL for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers and Obesity Treatment Agents containing a GLP-1 receptor agonist at: https://papdl.com/preferred-drug-list;

   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 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.

   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. Revisions to Dose and Duration of Therapy

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