

## Clinical Policy: GLP-1 Receptor Agonists

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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 GLP-1 Receptor Agonists is **medically necessary** when the following criteria are met:

### I. Requirements for Prior Authorization of Obesity Treatment Agents

**NOTE: GLP-1 Receptor Agonists are not covered for the treatment of overweight or obesity. GLP-1 Receptor Agonists are covered for the treatment of diagnoses that are indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or other medically accepted indications excluding treatment of overweight or obesity. Saxenda (liraglutide) will no longer be covered for any indication.**

#### A. Prescriptions That Require Prior Authorization

All prescriptions for GLP-1 Receptor Agonists must be prior authorized.

#### B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a GLP-1 Receptor Agonist, the determination of whether the requested prescription is medically necessary will take into account whether the member has the following:

1. For the treatment of diabetes, **one** of the following:
  - a. For a preferred GLP-1 Receptor Agonist for the treatment of diabetes, at least **one** of the following:
    - i. A diagnosis of diabetes
    - ii. A history of an antidiabetic drug (excluding metformin, SGLT-2 inhibitors, and drugs containing a GLP-1 receptor agonist) within the last 120 days
  - b. For a non-preferred GLP-1 Receptor Agonist for the treatment of diabetes, **all** of the following:
    - i. A diagnosis of diabetes,

- ii. A history of therapeutic failure of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved dose of the preferred GLP-1 Receptor Agonists approved or medically accepted for the beneficiary's diagnosis,
- iii. The prescribed GLP-1 Receptor Agonist is approved by the FDA for the treatment of diabetes;

*<sup>^</sup>For a request to change from one GLP-1 Receptor Agonist (e.g., a semaglutide product) to a different GLP-1 Receptor Agonist (e.g., a tirzepatide product) due to intolerance:* Must submit chart documentation that the following approaches were tried over a period of at least one month: dietary changes (e.g., eating apples, crackers, or mint- or ginger-based drinks 30 minutes after administering the GLP-1 Receptor Agonist), prescription antiemetics, and, for beneficiaries who tolerated lower doses of the GLP-1 Receptor Agonist, dose adjustment to remediate side effects experienced with higher doses of the GLP-1 Receptor Agonist.

**AND**

- 2. For a diagnosis other than diabetes, has chart documentation of **all** of the following:
  - a. **One** of the following:
    - i. For the treatment of moderate to severe obstructive sleep apnea (OSA), **all** of the following:
      - a) A recent body mass index (BMI) greater than or equal to 35 kg/m<sup>2</sup>,
      - b) A diagnosis of moderate to severe OSA confirmed within the last two years according to **one** of the following:
        - (i) The most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders)
        - (ii) A baseline apnea-hypopnea index greater than or equal to 15 events per hour,
      - c) At least **one** of the following clinical symptoms:
        - (i) Excessive daytime sleepiness (e.g., Epworth Sleepiness Scale [ESS  $\geq 10$ ])
        - (ii) Reduced-sleep related quality of life (e.g., snoring, nocturnal choking insomnia, disruption of partner's sleep, morning headaches, nocturia, etc.),
      - d) **One** of the following:

- (i) Utilization of positive airway pressure (PAP) with documented adherence to PAP treatment (defined as use of a PAP device for greater than or equal to four hours per night on 70% of nights during a consecutive 30-day period)
  - (ii) **Both** of the following:
    - a. If intolerant to PAP, must submit chart documentation that troubleshooting strategies have been tried to address barriers (e.g., provider consultation for mask-related issues, increasing humidity settings, addressing claustrophobia concerns)
    - b. If the beneficiary has a medical reason PAP cannot be used or is still intolerant to PAP despite troubleshooting strategies, utilization of or intolerance to an oral appliance for OSA,
- ii. For the reduction in risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke), **all** of the following:
  - a) Is prescribed the GLP-1 Receptor Agonist by or in consultation with an appropriate specialist (e.g., cardiologist, vascular surgeon, neurologist),
  - b) A recent BMI greater than or equal to 27 kg/m<sup>2</sup>,
  - c) **One** of the following:
    - (i) Prior myocardial infarction,
    - (ii) Prior stroke,
    - (iii) Peripheral arterial disease and at least **one** of the following:
      - a. Intermittent claudication with ankle-brachial index less than 0.85 (at rest),
      - b. A history of peripheral arterial revascularization procedure,
      - c. A history of amputation due to atherosclerotic disease,
  - d) The requested drug will be used in combination with optimized pharmacotherapy for established cardiovascular disease based on current consensus guidelines unless contraindicated or not tolerated,
- iii. For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), **all** of the following:
  - a) Is prescribed the GLP-1 Receptor Agonist by or in consultation with a hepatologist or gastroenterologist,

- b) Has a diagnosis of MASH with moderate to advanced liver fibrosis (consistent with stage F2 or F3 fibrosis) as confirmed by one of the following:
    - (i) Liver biopsy within the past three years
    - (ii) A recent FIB-4 index greater than or equal to 1.3 for beneficiaries less than 65 years of age (or greater than or equal to 2.0 for beneficiaries greater than or equal to 65 years of age) and **one** of the following:
      - a. Liver stiffness measurement by vibration controlled transient elastography (VCTE) (e.g., Fibroscan),
      - b. Magnetic resonance elastography (MRE),
      - c. Shear wave elastography (SWE),
      - d. Enhanced Liver Fibrosis (ELF) score,
  - c) Does not have significant alcohol use (defined as alcohol consumption of more than one drink per day for natal females or more than two drinks per day for natal males) or alcohol dependence,
  - d) The requested drug will be used in combination with optimized pharmacotherapy for established comorbid diseases (e.g., cardiovascular disease, dyslipidemia, diabetes, hypertension) based on current consensus guidelines unless contraindicated or not tolerated,
  - e) If currently taking Rezdiffra (resmetirom) with a plan to add concomitant therapy with a GLP-1 Receptor Agonist, failed to show improvement in liver fibrosis after a trial of Rezdiffra (resmetirom) for greater than or equal to 12 months,
- iv. For any other FDA-approved or medically accepted diagnoses (excluding treatment of overweight or obesity), **both** of the following:
- a) Has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines
  - b) The requested drug will be used in combination with optimized pharmacotherapy for the condition being treated based on current consensus guidelines unless contraindicated or not tolerated,
- b. **One** of the following:
- i. For a GLP-1 Receptor Agonist for the reduction in risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) or treatment of MASH, will use the requested GLP-1

- Receptor Agonist in combination with lifestyle changes and behavioral modifications (e.g., healthy diet and increased physical activity)
- ii. For a GLP-1 Receptor Agonist for an indication other than reduction in risk of major adverse cardiovascular events or treatment of MASH, a recent six-month trial of and plan to continue lifestyle changes and behavioral modifications (e.g., healthy diet and increased physical activity) or a medical reason why immediate treatment is necessary,
  - c. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
  - d. Does not have a contraindication to the prescribed drug,
  - e. For a non-preferred GLP-1 Receptor Agonist for a diagnosis other than diabetes, one of the following:
    - i. For Wegovy (semaglutide), **one** of the following:
      - a) For Wegovy (semaglutide) 2.4 mg, **one** of the following:
        - (i) **Both** of the following:
          - a. Dose titration to semaglutide 2 mg has been completed
          - b. A medical reason has been provided to support the need for the 2.4 mg dose
        - (ii) A history of therapeutic failure\* of the maximum FDA-approved dose of Ozempic (semaglutide)

***\*Therapeutic failure of a GLP-1 Receptor Agonist is defined as follows:*** Failure to achieve positive clinical outcome(s) as outlined in the renewal guidelines while utilizing the maximum FDA-approved dose of the GLP-1 Receptor Agonist with documentation of adherence to the GLP-1 Receptor Agonist in combination with lifestyle changes and behavioral modifications (e.g., healthy diet and increased physical activity). If the beneficiary is not at the maximum FDA-approved dose of the GLP-1 Receptor Agonist due to intolerance, must submit chart documentation that the following approaches were tried over a period of at least one month: dietary changes (e.g., eating apples, crackers, or mint- or ginger-based drinks 30 minutes after administering the GLP-1 Receptor Agonist), prescription antiemetics, and, for beneficiaries who tolerated lower doses of the GLP-1 Receptor Agonist, dose adjustment to remediate the side effects experienced with higher doses of the GLP-1 Receptor Agonist.

- b) For all other strengths of Wegovy (semaglutide), a history of therapeutic failure\* of Ozempic (semaglutide) that would not be expected to occur with the requested drug,
- ii. For Mounjaro (tirzepatide), a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses of Ozempic (semaglutide) and Wegovy (semaglutide),

***<sup>^</sup>For a request to change from one GLP-1 Receptor Agonist (e.g., a semaglutide product) to a different GLP-1 Receptor Agonist (e.g., a tirzepatide product) due to intolerance:*** Must submit chart documentation that the following approaches were tried over a period of at least one month: dietary changes (e.g., eating apples, crackers, or mint- or ginger-based drinks 30 minutes after administering the GLP-1 Receptor Agonist), prescription antiemetics, and, for beneficiaries who tolerated lower doses of the GLP-1 Receptor Agonist, dose adjustment to remediate side effects experienced with higher doses of the GLP-1 Receptor Agonist.

- iii. For Zepbound (tirzepatide), a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses of Ozempic (semaglutide), Wegovy (semaglutide), and Mounjaro (tirzepatide) that would not be expected to occur with the requested drug,
- iv. For all other non-preferred GLP-1 Receptor Agonists, a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses of Ozempic (semaglutide), Wegovy (semaglutide), and Mounjaro (tirzepatide) that would not be expected to occur with the requested drug;

**AND**

- 3. For therapeutic duplication of a GLP-1 receptor agonist when there is a record of a recent paid claim for another GLP-1 receptor agonist or a DPP-4 inhibitor in the point-of-sale online claims adjudication system, **one** of the following:
  - a. Is being transitioned to or from another GLP-1 receptor agonist or a 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 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 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 GLP-1 RECEPTOR AGONISTS: The determination of medical necessity of a request for renewal of a prior authorization for a GLP-1 Receptor Agonist that was previously approved will take into account whether the beneficiary has the following:

**NOTE: GLP-1 Receptor Agonists are not covered for the treatment of overweight or obesity. GLP-1 Receptor Agonists are covered for the treatment of diagnoses that are indicated in the FDA-approved package labeling or other medically accepted indications excluding treatment of overweight or obesity. Saxenda (liraglutide) will no longer be covered for any indication.**

1. For the treatment of diabetes, **one** of the following:
  - a. For a preferred GLP-1 Receptor Agonist for the treatment of diabetes, at least **one** of the following:
    - i. A diagnosis of diabetes
    - ii. A history of an antidiabetic drug (excluding metformin, SGLT-2 inhibitors, and drugs containing a GLP-1 receptor agonist) within the last 120 days
  - b. For a non-preferred GLP-1 Receptor Agonist for the treatment of diabetes, all of the following:
    - i. A diagnosis of diabetes,
    - ii. A history of therapeutic failure of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved dose of the preferred GLP-1 Receptor Agonists approved or medically accepted for the beneficiary's diagnosis,
    - iii. The prescribed GLP-1 Receptor Agonist is approved by the FDA for the treatment of diabetes;

***<sup>^</sup>For a request to change from one GLP-1 Receptor Agonist (e.g., a semaglutide product) to a different GLP-1 Receptor Agonist (e.g., a tirzepatide product) due to intolerance:*** Must submit chart documentation that the following approaches were tried over a period of at least one month: dietary changes (e.g., eating apples, crackers, or mint- or ginger-based drinks 30 minutes after administering the GLP-1 Receptor Agonist), prescription antiemetics, and, for beneficiaries who tolerated lower doses of the GLP-1 Receptor Agonist, dose adjustment to remediate side effects experienced with higher doses of the GLP-1 Receptor Agonist.



AND

2. For a non-preferred GLP-1 Receptor Agonist for a diagnosis other than diabetes, **one** of the following:
  - a. For Wegovy (semaglutide), **one** of the following:
    - i. For Wegovy (semaglutide) 2.4 mg, **one** of the following:
      - a) **Both** of the following:
        - (i) Dose titration to semaglutide 2 mg has been completed
        - (ii) A medical reason has been provided to support the need for the 2.4 mg dose
      - b) A history of therapeutic failure\* of the maximum FDA-approved dose Ozempic (semaglutide)
    - ii. For all other strengths of Wegovy (semaglutide), a history of therapeutic failure\* of Ozempic (semaglutide) that would not be expected to occur with the requested drug,
  - b. For Mounjaro (tirzepatide), a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses Ozempic (semaglutide) and Wegovy (semaglutide),
  - c. For Zepbound (tirzepatide), a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses of

***\*Therapeutic failure of a GLP-1 Receptor Agonist is defined as follows:*** Failure to achieve positive clinical outcome(s) as outlined in number 3. of the renewal guidelines below while utilizing the maximum FDA-approved dose of the GLP-1 Receptor Agonist with documentation of adherence to the GLP-1 Receptor Agonist in combination with lifestyle changes and behavioral modifications (e.g., healthy diet and increased physical activity). If the beneficiary is not at the maximum FDA-approved dose of the GLP-1 Receptor Agonist due to intolerance, must submit chart documentation that the following approaches were tried over a period of at least one month: dietary changes (e.g., eating apples, crackers, or mint- or ginger-based drinks 30 minutes after administering the GLP-1 Receptor Agonist), prescription antiemetics, and, for beneficiaries who tolerated lower doses of the GLP-1 Receptor Agonist, dose adjustment to remediate the side effects experienced with higher doses of the GLP-1 Receptor Agonist.



Ozempic (semaglutide), Wegovy, (semaglutide), and Mounjaro (tirzepatide) that would not be expected to occur with the requested drug,

- d. For all other non-preferred GLP-1 Receptor Agonists, a history of therapeutic failure of or a contraindication or an intolerance to the maximum FDA-approved doses of Ozempic (semaglutide), Wegovy (semaglutide), and Mounjaro (tirzepatide) that would not be expected to occur with the requested drug;

**AND**

- 3. For diagnoses other than diabetes, has chart documentation of **all** of the following:
  - a. **One** of the following:
    - i. For the reduction in risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke), **both** of the following:
      - a) Is prescribed the GLP-1 Receptor Agonist by or in consultation with an appropriate specialist (e.g., cardiologist, vascular surgeon, neurologist)
      - b) The requested drug will be used in combination with optimized pharmacotherapy for established cardiovascular disease based on current consensus guidelines unless contraindicated or not tolerated,
    - ii. For the treatment of MASH, **all** of the following:
      - a) Is prescribed the GLP-1 Receptor Agonist by or in consultation with a hepatologist or gastroenterologist,
      - b) Does not have significant alcohol use (defined as alcohol consumption of more than one drink per day for natal females or more than two drinks per day for natal males) or alcohol dependence,
      - c) The requested drug will be used in combination with optimized pharmacotherapy for established comorbid diseases (e.g., cardiovascular disease, dyslipidemia, diabetes, hypertension) based on current consensus guidelines unless contraindicated or not tolerated,
      - d) If the beneficiary has been using the GLP-1 Receptor Agonist for greater than or equal to one year, has documentation of **one** of the following:
        - (i) Resolution of steatohepatitis and improvement or no worsening of liver fibrosis
        - (ii) Improvement of liver fibrosis and no worsening of steatohepatitis,
  - iii. For the treatment of moderate to severe OSA, **all** of the following:

- a) **One** of the following:
  - (i) The beneficiary has been using the GLP-1 Receptor Agonist for less than six months and has documentation of lifestyle changes and behavioral modifications (e.g., healthy diet and increased physical activity)
  - (ii) If the beneficiary has been using the GLP-1 Receptor Agonist for greater than or equal to six months, **one** of the following:
    - a. If initial dose titration has been completed and the beneficiary has been using the GLP-1 Receptor Agonist for at least three consecutive months at the maximum tolerated dose, has 5% total body weight loss and documentation of dietary changes
    - b. If initial dose titration has not been completed and/or the beneficiary has been using the GLP-1 Receptor Agonist for less than three consecutive months at the maximum tolerated dose and the beneficiary has documentation of dietary changes, the reviewer may approve up to a three-month trial of the requested GLP-1 Receptor Agonist at the maximum tolerated dose,
- b) **One** of the following:
  - (i) Utilization of PAP with documented adherence to PAP treatment (defined as use of PAP devices for four or more hours per night on 70% of nights during a consecutive 30-day period) unless PAP is no longer recommended
  - (ii) If the beneficiary has a medical reason PAP cannot be used or is intolerant to PAP despite troubleshooting strategies, utilization of or intolerance to an oral appliance for OSA unless an oral device is no longer recommended,
- c) If the beneficiary has been using the GLP-1 Receptor Agonist for greater than or equal to one year, has documentation of improvement in OSA symptoms since initiating the requested drug (e.g., decrease in the apnea-hypopnea index number of events per hour from baseline, improvement in daytime sleepiness),
- iv. For any other FDA-approved or medically accepted diagnoses (excluding treatment of overweight or obesity), **both** of the following:
  - a) The requested drug will be used in combination with optimized pharmacotherapy for the condition being treated based on current consensus guidelines unless contraindicated or not tolerated

- b) If the beneficiary has been using the GLP-1 Receptor Agonist for at least three consecutive months at the maximum tolerated dose, has chart documentation demonstrating **one** of the following based on prescriber's assessment:
  - (i) Improvement or stabilization of the beneficiary's condition
  - (ii) Continues to benefit from therapy
- b. Is continuing lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity),
- c. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- d. Does not have a contraindication to the prescribed drug,
- e. If the request is for a different GLP-1 Receptor Agonist, **one** of the following:
  - i. For a non-preferred GLP-1 Receptor Agonist, **one** of the following:
    - a) For Wegovy (semaglutide), **one** of the following:
      - (i) For Wegovy (semaglutide) 2.4 mg, **one** of the following:
        - a. **Both** of the following:
          - 1. Dose titration to semaglutide 2 mg has been completed
          - 2. A medical reason has been provided to support the need for 2.4 mg dose
        - b. A history of therapeutic failure\* of the maximum FDA-approved dose Ozempic (semaglutide)
      - (ii) For all other strengths of Wegovy (semaglutide), a history of therapeutic failure\* of Ozempic (semaglutide) that would not be expected to occur with the requested drug,
    - b) For Mounjaro (tirzepatide), a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses of Ozempic (semaglutide) and Wegovy (semaglutide),
    - c) For Zepbound (tirzepatide), a history of therapeutic failure\* of or a contraindication or an intolerance<sup>^</sup> to the maximum FDA-approved doses of Ozempic (semaglutide), Wegovy (semaglutide), and Mounjaro (tirzepatide) that would not be expected to occur with the requested drug,

- d) For all other non-preferred GLP-1 Receptor Agonists, a history of therapeutic failure of or a contraindication or an intolerance to the maximum FDA-approved doses of Ozempic (semaglutide), Wegovy (semaglutide), and Mounjaro (tirzepatide) that would not be expected to occur with the requested drug
- ii. For a change from one preferred GLP-1 Receptor Agonist to another preferred GLP-1 Receptor Agonist, a rationale for the change in therapy;

**AND**

- 4. For therapeutic duplication of a GLP-1 receptor agonist when there is a record of a recent paid claim for another GLP-1 receptor agonist or a DPP-4 inhibitor in the point-of-sale online claims adjudication system, **one** of the following:
  - a. Is being transitioned to or from another GLP-1 receptor agonist or a 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 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 PA.CP.PMN.59 Quantity Limit Override.

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 GLP-1 Receptor Agonist. 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. Dose and Duration of Therapy

Prescriptions for GLP-1 Receptor Agonists will be limited to a one-month supply per fill.

Requests for prior authorization of GLP-1 Receptor Agonists will be approved as follows:

1. For a GLP-1 Receptor Agonist for a diagnosis of diabetes, requests will be approved for up to 12 months.
2. For a GLP-1 Receptor Agonist for a diagnosis of OSA, requests will be approved for up to six months unless otherwise specified in Section B.
3. For GLP-1 Receptor Agonists for all indications other than diabetes or OSA (excluding treatment of overweight or obesity), requests will be approved for up to six months.

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Reviews, Revisions, and Approvals	Date
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