# Expanded Indications GLP-1/GIP Prior Authorization with Quantity Limit

## FDA APPROVED INDICATIONS AND DOSAGE

| Agent(s) | FDA Indication(s) | Notes | Ref# |
|---|---|---|---|
| Wegovy®<br><br>(semaglutide)<br><br>Subcutaneous injection solution | In combination with a reduced calorie diet and increased physical activity:<br><br>• To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight<br>• To reduce excess body weight and maintain weight reduction long term in:<br>o Adults and pediatric patients aged 12 years and older with obesity<br>o Adults overweight in the presence of at least one weight-related comorbid condition<br><br>Limitations of Use: Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended | | 2 |
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*See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm*

## Target Agents

Wegovy (semaglutide)

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| | **Initial Evaluation**<br><br>1. **Target Agent(s)** will be approved when ALL the following are met:<br><br>A. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:<br>1. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND**<br>2. The patient has a history of ONE of the following: (medical records required)<br>A. Myocardial infarction **OR**<br>B. Stroke **OR**<br>C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**<br>3. The patient has a BMI greater than or equal to 30 kg/m^2 **AND**<br>4. The patient does NOT have type 2 diabetes, **AND**<br>5. The patient's age is 45 years or over **AND**<br>6. ONE of the following: |

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|---|---|
| | A. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**<br>B. The patient is being managed for tobacco cessation **AND**<br>7. ALL of the following:<br>A. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**<br>B. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**<br>C. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND**<br>8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>2. The patient has an FDA labeled indication, and ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. There is support for using the requested agent for the patient's age for the requested indication **AND**<br>3. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:**<br><br>12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>[Note: patients not previously approved for the requested agent for the requested indication will require initial evaluation review]<br><br>Patient must be adherent to medication for continued therapy.<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**<br>2. If the requested agent is Wegovy, then requested dose is 1.7 mg or 2.4 mg **AND**<br>3. The following:<br><br>A. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:<br>1. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND**<br>2. The patient continues to have a BMI greater than or equal to 30 kg/m^2 **AND**<br>3. The patient does NOT have type 2 diabetes **AND**<br>4. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **AND**<br>5. ALL of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**<br>B. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**<br>C. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND**<br>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND<br>5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>6. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| Universal QL | **Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit OR<br>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:<br>A. BOTH of the following:<br>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND<br>2. There is support for therapy with a higher dose for the requested indication OR<br>B. BOTH of the following:<br>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND<br>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR<br>C. BOTH of the following:<br>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND<br>2. There is support for therapy with a higher dose for the requested indication<br><br>**Length of Approval**:<br><br>• Initial Approval: 12 months<br><br>• Renewal Approval: 12 months |