# PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>WEIGHT LOSS MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAND NAME (generic)</td>
<td>ZEPBOUND (tirzepatide)</td>
</tr>
</tbody>
</table>

**Status: CVS Caremark® Criteria**  
**Type: Initial Prior Authorization with Quantity Limit**

## POLICY

### FDA-APPROVED INDICATIONS

Zepbound is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m² or greater (obesity) or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

**Limitations of Use**

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

## COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management in an adult
  
  **AND**
  
  - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
    
    **AND**
    
    - The patient has a body mass index (BMI) greater than or equal to 30 kg/m². [ACTION REQUIRED: Documentation is required for approval.]
    
  OR

  - The patient has a body mass index (BMI) greater than or equal to 27 kg/m². [ACTION REQUIRED: Documentation is required for approval.]
    
    **AND**
    
    - The patient has at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [ACTION REQUIRED: Documentation is required for approval.]
    
  OR

  - The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose
    
    **AND**

Zepbound PA with Limit Policy UDR 11-2023.docx

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- The patient has lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. [ACTION REQUIRED: Documentation is required for approval.]

Quantity Limits apply.

### QUANTITY LIMIT

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>1 Month Limit*</th>
<th>3 Month Limit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zepbound (tirzepatide)</td>
<td>2.5 mg/0.5 mL</td>
<td>2 mL (1 package of 4 pens each) / 21 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 mg/0.5 mL</td>
<td></td>
<td>6 mL (3 packages of 4 pens each) / 63 days</td>
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<tr>
<td></td>
<td>7.5 mg/0.5 mL</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>10 mg/0.5 mL</td>
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<tr>
<td></td>
<td>12.5 mg/0.5 mL</td>
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<tr>
<td></td>
<td>15 mg/0.5 mL</td>
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*The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

Duration of Approval (DOA):
- 6192-C: Initial therapy DOA: 8 months; Continuation of therapy DOA: 12 months

### REFERENCES