| Reference number(s) |
| --- |
| 6192-C |

# Initial Prior Authorization with Quantity Limit
# Zepbound
# Weight Loss Management

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths except 2.5 mg/0.5 mL and 5 mg/0.5 mL vials that are covered under the LillyDirect manufacturer program. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Zepbound | tirzepatide |

## Indications

### FDA-approved Indications

Zepbound is indicated in combination with a reduced-calorie diet and increased physical activity:

- To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.
- To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

### 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.

# Coverage Criteria

## Obstructive Sleep Apnea

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a current body mass index (BMI) greater than or equal to 30 $kg/m^2$. [ACTION REQUIRED: Documentation is required for approval.]

## Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term in an adult when ALL of the following criteria are met:

- 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.
- The patient meets ONE of the following:
    - The patient has a baseline body mass index (BMI) greater than or equal to 30 $kg/m^2$. [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.]
    - The patient has a baseline BMI greater than or equal to 27 $kg/m^2$. [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] In addition, the following criteria is met:
        - 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.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their weight-related comorbid condition(s) at the start of any drug therapy.]

# Continuation of Therapy

## Obstructive Sleep Apnea

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has achieved or maintained a positive response to treatment from baseline, evidenced by a decrease in OSA symptoms.
- The patient is being treated with a maintenance dosage, 10 mg or 15 mg once weekly, of the requested drug.

## Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term in an adult when ALL of the following criteria are met:

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

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.

| Drug | Dosage | 1 Month Limit | 3 Month Limit |
| --- | --- | --- | --- |
| Zepbound (tirzepatide) | 2.5 mg / 0.5 mL | 2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days | 6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days |

| Drug | Dosage | 1 Month Limit | 3 Month Limit |
|---|---|---|---|
| Zepbound (tirzepatide) | 5 mg / 0.5 mL | 2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days | 6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days |
| Zepbound (tirzepatide) | 7.5 mg / 0.5 mL | 2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days | 6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days |
| Zepbound (tirzepatide) | 10 mg / 0.5 mL | 2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days | 6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days |
| Zepbound (tirzepatide) | 12.5 mg / 0.5 mL | 2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days | 6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days |
| Zepbound (tirzepatide) | 15 mg / 0.5 mL | 2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days | 6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days |

# Duration of Approval (DOA)

- 6192-C:
  - Obstructive Sleep Apnea (OSA): Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months
  - Reduction in excess body weight, maintenance of weight reduction long term: Initial therapy DOA: 8 months; Continuation of therapy DOA: 12 months

# References

1. Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC; December 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 28, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/28/2024).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. Circulation. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(2):342–362.

6. Malhorta A, Grunstein RR, Fietze I, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity. New Engl J Med. 2024;391:1193-1205.
7. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.