

ALASKA MEDICAID
Clinical Criteria for Use

Mounjaro[®], Zepbound[®]
(tirzepatide)

FDA INDICATIONS AND USAGE¹

Mounjaro[®] is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated

- as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
- To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.

Zepbound[®] is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced calorie diet and 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.
- ❖ Non-covered indication per regulation (7 AAC 105.110, 7 AAC 120.112) please see Denial Criteria below for further information.

APPROVAL CRITERIA^{1,2,3,4}

Mounjaro[®]

1. Patient meets FDA labeled age **AND;**
2. Patient has the diagnosis of diabetes mellitus type II **AND;**
3. Patient has the diagnosis of diabetes mellitus type II and one or more of the following:
 - a. Patient Hemoglobin A1c (HbA1c) >7% within the last 60 days
 - b. Patient has the diagnosis of ASCVD **AND;**
4. Provider has submitted a current comprehensive diabetes care plan **AND;**
5. Patient has tried metformin at maximum tolerated dose for a minimum of three months with inadequate results or has a documented clinical contraindication to metformin **AND;**
6. Patient has a clinically documented trial of two Alaska Medicaid preferred GLP-1 medications at maximum tolerated dose for a minimum of three months with inadequate results or a documented adverse reaction to both leading to discontinuation.
7. The prescriber attests that if adequate clinical control of the FDA-approved covered indication has been achieved, subsequent dose escalation will not be pursued solely to promote additional weight loss.

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Zepbound®

1. Patient meets FDA labeled age **AND**;
2. Patient body mass index is ≥ 30 **AND**;
3. Patient has the diagnosis of moderate to severe obstructive sleep apnea, defined as an apnea-hypopnea index (AHI) greater than 15 events per hour, confirmed by a documented sleep study.
4. The prescriber attests that if adequate clinical control of the FDA-approved covered indication has been achieved, subsequent dose escalation will not be pursued solely to promote additional weight loss.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Medication is being prescribed for purposes of weight control (excluded from coverage under Alaska Administrative Code 7 AAC 105.110 and 7 AAC 120.112) **OR**;
3. Patient has a personal or family history of Medullary Thyroid Cancer (MTC) **OR**;
4. Patient has been diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) **OR**;
5. Patient has been diagnosed with severe gastroparesis **OR**;
6. Drug is being prescribed for concomitant use with another GLP-1 or GIP agonist product.

CAUTIONS¹

- The most common adverse reactions reported include nausea, vomiting, diarrhea, abdominal pain, and constipation.
- Acute Pancreatitis has been observed in patients treated with tirzepatide, discontinue if pancreatitis suspected
- Diabetic retinopathy complications have been reported in clinical trials
- Concomitant use with insulin or insulin secretagogues may increase the risk of hypoglycemia
- Severe gastrointestinal adverse reactions have been reported
- Renal function should be assessed and monitored in patients reporting adverse reactions that could lead to volume depletion
- Tirzepatide has been associated with acute gallbladder disease
- Incidents of pulmonary aspiration have been reported during general anesthesia or deep sedation.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization: up to 12 months*

*Note: prior authorizations are drug and strength specific. Any request for a change in strength may require a new prior authorization accompanied by sufficient supporting materials to establish the medical necessity of the requested change.

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QUANTITY LIMIT

- Four pens per month

REFERENCES / FOOTNOTES:

1. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; August 2026
2. Zepbound (tirzepatide) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; April 2026
3. Malhotra A, Grunstein RR, Fietze I, et. al. Tirzepatide for the treatment of Obstructive Sleep Apnea and Obesity. N Engl J Med 2024; 391:1193-1205.
4. Nicholls SJ, Pavo I, Bhatt, DL, et.al. Cardiovascular Outcomes with Tirzepatide versus Dulaglutide in Type 2 Diabetes. N Engl J Med 2025; 393: 2409-2420.
5. American Diabetes Association. 2026 Standards of Care in Diabetes. Diabetes Care. 2025; 49: S1-S371
6. NCT05412004. Obstructive Sleep Apnea Master Protocol GPIF: A study of Tirzepatide (LY3298176) in Participants with Obstructive Sleep Apnea (SURMOUNT-OSA). Updated August 30, 2025.