

ALASKA MEDICAID
Clinical Criteria for Use

Ozempic[®], Wegovy[®]
(semaglutide)

FDA INDICATIONS AND USAGE^{1,2,3}

Ozempic[®] is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease
- to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease

Ozempic[®] tablets is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:

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

Wegovy[®] is a glucagon-like peptide-1 (GLP-1) receptor agonist. WEGOVY[®] injection is indicated in combination with a reduced calorie diet and increased physical activity:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
- ❖ To reduce excess body weight and maintain weight reduction long term in:
 - ❖ Adults and pediatric patients aged 12 years and older with obesity.
 - ❖ Adults with overweight in the presence of at least one weight-related comorbid condition.
- For the treatment of noncirrhotic metabolic dysfunction associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. This indication is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

Wegovy[®] tablets are indicated in combination with a reduced calorie diet and increased physical activity:

- To reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
- ❖ To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.

- ❖ Non-covered indication per regulation (7 AAC 105.110, 7 AAC 120.112) please see Denial Criteria below for further information.

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APPROVAL CRITERIA^{1,2,3,4,5,6,7,8}

Ozempic® injection and Ozempic® tablets:

1. Patient meets FDA labeled age **AND**;
2. Qualifying ICD10 for a covered indication has been submitted on point-of-sale claims **OR**;
3. Patient has the diagnosis of diabetes mellitus type II and one or more of the following:
 - Patient Hemoglobin A1c (HbA1c) >7% within the last 60 days
 - Patient has the diagnosis of ASCVD
 - Patient has the diagnosis of chronic kidney disease with eGFR <60ml/min/1.73 m² and UACR > 30mg/g for a minimum three months **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
6. 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.

Wegovy® injection and Wegovy® tablets:

1. Patient meets FDA labeled age **AND**;
2. Patient has a Body Mass Index (BMI) ≥ 25 and documented diagnosis of one or more of the following:
 - Metabolic dysfunction-associated steatohepatitis with moderate to advanced liver fibrosis (stage F2 to F3) (Wegovy® injection only)
 - Prior myocardial infarction
 - Prior ischemic or hemorrhagic stroke
 - Chronic ischemic heart disease
 - Peripheral artery disease
 - Atherosclerosis
3. 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 CRITERIA^{1,2,3}

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

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CAUTIONS^{1,2}

- The most common adverse reactions reported include nausea, vomiting, diarrhea, abdominal pain, and constipation.
- Acute Pancreatitis has been observed in patients treated with semaglutide, 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
- Semaglutide 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.

QUANTITY LIMIT

- Four pens per month or 34 tablets per 34 days

REFERENCES / FOOTNOTES:

1. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk, Inc.; May 2026
2. Ozempic tablet (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk, Inc.; January 2026
3. Wegovy (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk, Inc.; June 2026
4. Lincoff AM, Brown-Frandsen K, Colhoun HM, et.al. Semaglutide and cardiovascular outcomes in obesity without diabetes. N Engl J Med 2023; 389: 2221-2232.
5. Marso SP, Bain SC, Consoli A, et. al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. 2016; 375:19: 1834-1844.
6. NCT03819153 A Research Study to See How Semaglutide Works Compared to Placebo in People With Type 2 Diabetes and Chronic Kidney Disease (FLOW)
7. Sanyal AJ, Newsome PN, Kliers, I, et.al. Phase 3 Trial of Semaglutide in Metabolic Dysfunction-Associated Steatohepatitis. N Engl J Med 2025; 392: 2089-2099
8. American Diabetes Association. 2026 Standards of Care in Diabetes. Diabetes Care. 2025; 49: S1-S371

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