

Criteria-Based Consultation Prescribing Program KAISER PERMANENTE NORTHWEST REGION CRITERIA FOR DRUG COVERAGE

Injectable semaglutide (Ozempic)

Notes:

- Ozempic is covered under the prescription drug benefit for weight loss **ONLY for Kaiser Northwest members with coverage for medications used to treat weight loss**. Others pay member cash price.
- Contact Pharmacy Services in your home region to confirm your benefits for weight loss medications.
- Quantity Limits: Yes
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ^ Adequate trial is defined as a 3-month treatment duration
- # For patients aged 18-64, recommend A1c goal of < 7.0% unless significant co-morbidities (history of dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/HF, or ASCVD). For patients aged 65 or older, consider A1c goal of < 8.0%
- ** Per Kaiser National Clinical Practice Guideline, clinical ASCVD (secondary prevention) includes acute coronary syndrome (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral artery disease (PAD), all of atherosclerotic origin
 - Subclinical atherosclerosis, such as elevated coronary artery calcium or aortic atherosclerosis, or patients at high risk for ASCVD (primary prevention) are NOT included in the definition of clinical ASCVD
- @Hydrophilic statin includes pravastatin or rosuvastatin. Low intensity statin includes simvastatin 10 mg, lovastatin 20 mg, or pravastatin 10-20 mg

Initiation (new start) criteria: Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for when the following criteria are met:

Diagnosis of Type 2 Diabetes Mellitus and Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**

- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- On maximally tolerated metformin dose or intolerance* or contraindication to metformin (includes both metformin IR and XR)
- Intolerance* or contraindication to an SGLT-2 inhibitor (e.g. Jardiance)

-OR-

Diagnosis of Type 2 Diabetes Mellitus (approved for 12 months)

- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

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- On maximally tolerated metformin dose or intolerance* or contraindication to metformin (includes both metformin IR and XR)
- Has failed to reach A1c goal[#] after an adequate trial[^] of an SGLT-2 inhibitor
 - Trial of SGLT-2 inhibitor not required for patients with:
 - most recent A1c greater than 8.5%
 - eGFR less than 45 mL/min (*SGLT-2s are strongly recommended for renal protection but are not effective for glycemic lowering in patients with reduced renal function*)
 - age 18 years or younger
 - contraindication to SGLT-2
- Meets one of the following criteria:
 - Most recent A1c is above but within 2% of patient's designated goal[#]
 - Most recent A1c is above patient's designated goal[#] and patient is on insulin at a total daily dose of greater than or equal to 0.5 units/kg/day
- Meets one of the following criteria:
 - Has contraindication/intolerance to or is currently taking maximum dose sulfonylurea and any dose of pioglitazone for at least 3 months
 - Patient is on insulin at a total daily dose of greater than or equal to 0.5 units/kg/day and has failed to reach A1c goal[#] after an adequate trial[^] of pioglitazone unless intolerance/contraindication
 - Pediatric patient aged 12-19 years

Initiation (new start) criteria in adult patients for chronic weight management:

Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 4 months when the following criteria are met:

- Patient has a prescription drug insurance benefit that covers medications used to lose weight; AND
- Diagnosis for chronic weight management; AND
- Patient is 18 years of age or older; AND
- Patient's current weight and BMI are documented in the encounter in which semaglutide (Ozempic) is ordered; AND
- Patient is currently following a diet and exercise program; AND

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- BMI greater than or equal to 30 kg/m² or BMI greater than or equal to 27 kg/m² AND has at least one of the following comorbid conditions documented:
 - Hypertension
 - Diabetes
 - Hyperlipidemia
- AND-
- Patient has failed an adequate trial[^] to at least two of the following medications or medication combination therapies, or patient has an allergy, intolerance, or contraindication to all the following therapies:
 - phentermine
 - diethylpropion
 - phentermine + topiramate or phentermine/topiramate (Qsymia)
 - naltrexone + bupropion or naltrexone/bupropion (Contrave)

Initiation (new start) criteria in pediatric patients for obesity: Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 4 months when the following criteria are met:

- Patient has a prescription drug insurance benefit that covers medications used to lose weight; **AND**
 - Diagnosis of class 2 or class 3 obesity; **AND**
 - Patient is 12 to 17 years of age or older and is at least Tanner 2; **AND**
 - Patient's current weight and BMI are documented within the last month from the date in which semaglutide (Wegovy) is ordered; **AND**
 - Patient is currently following a diet and exercise program **AND**
 - BMI greater than or equal to 35 kg/m² or at least 120% of 95th percentile
- AND-
- Patient has failed an adequate trial[^] to at least two of the following medications or medication combination therapies, or patient has an allergy, intolerance, or contraindication to all the following therapies:
 - phentermine
 - topiramate
 - phentermine + topiramate or phentermine/topiramate (Qsymia)

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Initiation (new start) criteria for cardiovascular risk reduction: Non-formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient does not have diabetes; **AND**
- BMI 27 or greater; **AND**
- Established cardiovascular disease defined as having at least one of the following:
 - History of myocardial infarction (MI)
 - History of stroke
 - Symptomatic peripheral arterial disease, as evidenced by intermittent claudication with ankle-brachial index less than 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease

AND

- Documentation of one of the following regarding statins:
 - Receiving maximally tolerated dose of statin therapy
 - History of statin intolerance defined as mild adverse effect to a trial of 3 or more statins or a trial of 2 statins comprised of 1 hydrophilic statin and 1 low intensity statin[@]
 - History of severe adverse effect to statin such as statin-induced rhabdomyolysis or statin-induced necrotizing myositis

Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for when the following criteria are met:

Diagnosis of Type 2 Diabetes Mellitus and Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**

- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- On maximally tolerated metformin dose or intolerance* or contraindication to metformin (includes both metformin IR and XR)
- Intolerance* or contraindication to an SGLT-2 inhibitor

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-OR-

Diagnosis of Type 2 Diabetes Mellitus without ASCVD (approved for 12 months)

- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- On maximally tolerated metformin dose or intolerance* or contraindication to metformin (includes both metformin IR and XR)
- Taking or has a contraindication to an SGLT-2 inhibitor
 - Trial of SGLT-2 inhibitor not required for patients with:
 - most recent A1c greater than 8.5%
 - eGFR less than 45 mL/min
 - age 18 years or younger
 - contraindication to SGLT-2
- And meets one of the following criteria:
 - Has contraindication/intolerance* to or is currently using maximum dose sulfonylurea and any dose of pioglitazone
 - Patient is on insulin at a total daily dose of greater than or equal to 0.5 units/kg/day and is on any dose of pioglitazone unless intolerance/contraindication
 - Pediatric patient aged 12-19 years

-OR-

- Patient has a prescription drug insurance benefit that covers medications used to lose weight; **AND** Patient is using for chronic weight management

Continued use criteria when used for Type 2 Diabetes without diagnosis of ASCVD: formulary **semaglutide (Ozempic)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- A1c is either at goal[#] or has decreased by at least 0.5% or more from baseline prior to starting GLP-1 therapy unless the patient is on insulin at a total daily dose of greater than or equal to 0.5 units/kg/day or pediatric patient aged 12-19 years

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- New members continued on GLP-1 therapy will need to meet one of the following:
 - i. Maintain glycemic control if at goal or within 2% of designated A1c goal
 - ii. If A1c greater than 2% above goal at time of initial review, A1c has decreased by at least 0.5% unless patient is on insulin at a total daily dose of greater than or equal to 0.5 units/kg/day
- Adherence (greater than 80%) to prescribed diabetes medications

Continued use criteria (4 months after initiation and then every 12 months) when used for chronic weight management/obesity: Non-formulary **semaglutide (Ozempic)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient's updated weight and BMI are recently documented; **AND**
- Patient has achieved greater than 5% weight loss with the past 16 weeks from initiation (reviewed once); **OR**
 - Maintains greater than 5% weight loss thereafter (reviewed every 12 months)