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
- ** 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
- GMI = Glucose Management Indicator, an estimated A1c level based on continuous glucose monitoring data
- ***Does not apply to Medicare Part D patients

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

1) **Diagnosis of Type 2 Diabetes Mellitus and Clinical Atherosclerotic Cardiovascular Disease (ASCVD)****
   a) No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
   b) On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR
   c) Intolerance* or contraindication to SGLT-2 inhibitors
      - Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria
   d) Intolerance or contraindication to liraglutide
      - Note: If patient is currently on liraglutide, must meet the additional DM2 criteria

-OR-

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2) Adults (age 20+) with diagnosis of Type 2 Diabetes Mellitus

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

b) Not on insulin or on insulin at a total daily dose less than 0.5 units/kg/day, meets ALL of the following criteria:

i. Currently taking at least 2 of the following medications for at least 3 months[#]:
   1. Maximally tolerated dose of metformin
   2. Maximally tolerated dose of sulfonylurea (e.g. glipizide)
   3. Pioglitazone
   4. SGLT2 inhibitor

   [#] If not taking at least 2 of the above med options, needs to have an intolerance or contraindication to the remaining medications

ii. On maximum tolerated liraglutide dose (1.8 mg/day) or has contraindication or intolerance to liraglutide

iii. HbA1c or GMI remains greater than 6.9% but less than 10% after adequate trial^ of the therapies mentioned above

-OR-

c) On insulin at a total daily dose of 0.5 units/kg/day or more, meets ALL of the following criteria:

i. On maximally tolerated metformin dose or has contraindication/intolerance to metformin XR

ii. On maximum tolerated liraglutide dose (1.8 mg/day) or has contraindication or intolerance to liraglutide

iii. HbA1c or GMI remains greater than 6.9% after adequate trial^ of the therapies mentioned above

-OR-

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3) **Diagnosis of Type 2 Diabetes Mellitus AND Proteinuria**
   a) No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
   b) Persistent proteinuria defined as 2 or more measurements of urine albumin/creatinine ratio (ACR) greater than 300 mg/gm or protein creatinine ratio (PCR) greater than 0.5
   c) Estimated glomerular filtration rate (eGFR) of 30 mL/min/m2 or higher
   d) On maximally tolerated dose or allergy or intolerance to ACE inhibitor or ARB
   e) Allergy or intolerance to SGLT2 inhibitor therapy AND liraglutide
      - Note: If patient is currently on an SGLT-2 inhibitor and/or liraglutide, must meet the additional DM2 criteria

-OR-

4) **Members aged 12-19 years with diagnosis of Type 2 Diabetes Mellitus:**
   a) No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
   b) On maximally tolerated metformin dose or has contraindication/intolerance to metformin XR
   c) On maximum liraglutide dose (1.8 mg/day) or has contraindication/intolerance to liraglutide
   d) HbA1c or GMI remains greater than 6.9% but less than 10% after adequate trial^ of the therapies mentioned above unless patient is currently on insulin

5) **<u>Initiation (new start) criteria in adult patients for chronic weight management</u>:**
   Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:
   a) Patient has a prescription drug insurance benefit that covers medications used to lose weight; AND
   b) No personal or family history of medullary thyroid carcinoma (MTC) or Multi Endocrine Neoplasia syndrome type 2 (MEN 2)
   c) Diagnosis for chronic weight management; AND
   d) Patient is 18 years of age or older; AND
   e) Patient's current weight and BMI has been documented within the last 30 days approximately; AND
   f) Patient is currently following a diet and exercise program; AND
   g) BMI greater than or equal to 30 kg/m^2 or BMI greater than or equal to 27 kg/m^2 AND has at least one of the following comorbid conditions documented:

- Hypertension
- Diabetes Type 2
- Hyperlipidemia

-AND-

h) 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
   - topiramate
   - phentermine + topiramate or phentermine/topiramate (Qsymia)
   - naltrexone + bupropion or naltrexone/bupropion (Contrave)

6) **Initiation (new start) criteria in pediatric patients for obesity:** Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:
   a) Patient has a prescription drug insurance benefit that covers medications used to lose weight; AND
   b) No personal or family history of medullary thyroid carcinoma (MTC) or Multi Endocrine Neoplasia syndrome type 2 (MEN 2)
   c) Diagnosis of class 2 or class 3 obesity; AND
   d) Patient is 12 to 17 years of age and is at least Tanner 2; AND
   e) Patient's current weight and BMI has been documented within the last 30 days approximately; AND
   f) Patient is currently following a diet and exercise program; AND
   g) BMI greater than or equal to 35 kg/m^2 or at least 120% of 95^{th} percentile; AND
   h) 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)

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

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a) No personal or family history of medullary thyroid carcinoma (MTC) or Multi Endocrine Neoplasia syndrome type 2 (MEN 2)
b) Patient does not have diabetes; AND
c) BMI 27 or greater; AND
d) Patient is currently following a diet and exercise program; AND
e) Patient is 55 to 74 years of age; AND
f) Patient has a history of STEMI or Type 1 NSTEMI

8) **Initiation (new start) criteria in patients for obstructive sleep apnea (OSA) and do not have a diagnosis of diabetes:** Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:
   a) No personal or family history of medullary thyroid carcinoma (MTC) or Multi Endocrine Neoplasia syndrome type 2 (MEN 2)
   b) Patient does not have central or complex apnea; AND
   c) Patient has had a sleep study within the last 3 years and they have not lost more than 5% body weight since the time of the study (study weight is +/- 3 months from time of study); AND
   d) Diagnosis for severe sleep apnea (AHI 30 or greater); AND
   e) Patient is 18 years of age or older; AND
   f) Patient's current weight and BMI has been documented within the last 30 days approximately; AND
   g) Patient is currently following a diet and exercise program; AND
   h) BMI greater than or equal to 30 kg/m^2; AND
   i) 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
      - topiramate
      - phentermine + topiramate or phentermine/topiramate (Qsymia)
      - naltrexone + bupropion or naltrexone/bupropion (Contrave)

9) **Initiation (new start) criteria in patients for metabolic dysfunction-associated steatohepatitis (MASH):** Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

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a) No personal or family history of medullary thyroid carcinoma (MTC) or Multi Endocrine Neoplasia syndrome type 2 (MEN 2)
b) Diagnosis of metabolic dysfunction-associated steatohepatitis; **AND**
c) Hepatology provider consulted and endorsed use; **AND**
d) Patient is 18 years of age or older; **AND**
e) Patient has fibrosis stage F2 or F3 as determined by transient elastography (FibroScan), ultrasound elastography, magnetic resonance elastography (MRE), or liver biopsy within one year OR has history of known fibrosis stage F2 or F3 who is currently taking GLP-1 agonist and does not have fibrosis stage F4 (cirrhosis); **AND**
f) Patient has at least one of the following:
   - BMI ≥ 30 kg/m^2 or BMI 27-29 kg/m^2 plus diabetes type 2, hypertension or hyperlipidemia AND failed an adequate trial^ of at least two of the following medications or medication combination therapies with a goal of 7% to 10% weight loss, or patient has an allergy, intolerance, or contraindication to all the following therapies:
     i. Phentermine
     ii. Diethylpropion
     iii. Topiramate
     iv. phentermine + topiramate or phentermine/topiramate (Qsymia)
     v. naltrexone + bupropion or naltrexone/bupropion (Contrave)
   - Failed an adequate trial^ of formal weight loss program (without the use of oral weight loss medication) AND hepatology provider recommends use
   - Disease refractory to weight loss of 7-10%
   - Currently taking GLP-1 agonist
g) Patient is not taking resmetirom; **AND**
h) Patient does not have any of the following:
   - Regular use of drugs associated with metabolic dysfunction-associated steatotic liver disease (MASLD)
   - ALT/AST > 5 times upper limit of normal (ULN) that is likely from other etiology of chronic liver disease
   - Significant alcohol consumption defined as ≥ 7 drinks per week for females and ≥ 14 drinks for males
   - Active, serious medical disease with a likely life expectancy <2 years

Initiation (new start) criteria and criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:

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Initiation (new start) criteria and criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:
Formulary **semaglutide (Ozempic)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

a) Prescribed by an endocrinology, pediatric endocrinology, or bariatrics provider;
AND
b) Age 6 years or older;
AND
c) Diagnosis of 1 of the following:
- Obesity due to Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS). If VUS must be deemed highly suspicious by a medical geneticist

- Bardet-Biedl syndrome with documented disease-causing mutation confirmed by genetic testing or highly suspected based on review and evaluation by a medical geneticist

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:

10) Diagnosis of Type 2 Diabetes Mellitus and Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**
a) No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
b) On maximally tolerated metformin dose or intolerance* or contraindication to metformin (includes metformin XR)
c) Intolerance* or contraindication to SGLT-2 inhibitors
- Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria

d) Intolerance or contraindication to liraglutide
- Note: If patient is currently on liraglutide, must meet the additional DM2 criteria

-OR-

11) Adults (age 20+) with a diagnosis of Type 2 Diabetes Mellitus

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

b) Not on insulin or on insulin at a total daily dose less than 0.5 units/kg/day, meets the following criteria:
   i. Currently taking, or prior to GLP1 use has history of taking, at least 2 of the following medications
      - Maximally tolerated dose of metformin
      - Maximally tolerated dose of sulfonylurea (e.g. glipizide)
      - Pioglitazone
      - SGLT2 inhibitor
   ii. HbA1c or GMI is less than 10%

-OR-

c) Patient is on, or prior to GLP1 use has history of, insulin at a total daily dose 0.5 units/kg/day or more AND on maximally tolerated metformin dose or intolerance* or contraindication to metformin XR

-OR-

12) Diagnosis of Type 2 Diabetes Mellitus AND Proteinuria

a) No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
b) History of urine albumin/creatinine ratio (ACR) greater than 300 mg/gm or protein creatinine ratio (PCR) greater than 0.5
c) On maximally tolerated dose or allergy or intolerance to ACE inhibitor or ARB
d) Allergy or intolerance to SGLT2 inhibitors AND liraglutide
   - Note: If patient is currently on an SGLT-2 inhibitor and/or liraglutide, must meet the additional DM2 criteria

-OR-

13) Members aged 12-19 years with diagnosis of Type 2 Diabetes Mellitus:

a) No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
b) On maximally tolerated metformin dose or has contraindication/intolerance to metformin XR
c) HbA1c or GMI at less than 10% if not on insulin

-OR-

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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 12 months when the following criteria are met:

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

-OR-

15) Patient is using for obstructive sleep apnea (OSA)

-OR-

16) Patient is using for metabolic dysfunction-associated steatohepatitis (MASH)

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17) **Continued use criteria (every 12 months) for patients previously reviewed and approved when used for chronic weight management/obesity or OSA:** Formulary **semaglutide (Ozempic)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:
    a) Patient's updated weight and BMI are recently documented; **AND**
    b) Achieved and maintained 5% or greater weight loss after starting semaglutide (Ozempic)

18) **Continued use criteria (every 12 months) for patients previously reviewed and approved when used for MASH:** Formulary **semaglutide (Ozempic)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:
    a) Patient does not have any of the following:
        - Fibrosis stage F4 or liver cirrhosis
        - Progression of liver disease (i.e. increased fibrosis stage from baseline) and on semaglutide for ≥ 18 months without further consultation with hepatology provider
        - Regular use of drugs associated with metabolic dysfunction-associated steatotic liver disease (MASLD)
        - Non-adherence to medication, recommended diet and lifestyle measures, abstinence of alcohol or follow-up labs and assessments
        - Active, serious medical disease with a likely life expectancy <2 years
    b) Updated fibrosis staging determined by transient elastography (FibroScan), ultrasound elastography, magnetic resonance elastography (MRE), or liver biopsy **AND** hepatology provider follow-up within 2 years after semaglutide initiation