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
- 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 (e.g. Jardiance)
      - Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria
   d) Intolerance or contraindication to liraglutide (Victoza)
      - Note: If patient is currently on liraglutide (Victoza), must meet the additional DM2 criteria

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-OR-

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

ii. On maximally tolerated sulfonylurea or has contraindication/intolerance to sulfonylureas

iii. On pioglitazone or has contraindication/intolerance to pioglitazone

iv. On an SGLT2 inhibitor (e.g. Jardiance) or has contraindication/intolerance SGLT2 inhibitors

- Note: SGLT2 inhibitor is not required if patient has CKD3 with eGFR less than 45 mL/min/m^2

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

vi. HbA1c or GMI remains above, but within 2% of, patient's designated goal[#] after adequate trial^ of the therapies mentioned above

-OR-

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

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

ii. On an SGLT2 inhibitor (e.g. Jardiance) or pioglitazone or has contraindication/intolerance to both

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

iv. HbA1c or GMI remains above patient's designated goal 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 (i.e. Jardiance) AND liraglutide (Victoza)
   - Note: If patient is currently on an SGLT-2 inhibitor and/or liraglutide (Victoza), 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 above, but within 2% of, patient's designated goal[#] after adequate trial^ of the therapies mentioned above
   - If patient on insulin, A1c only needs to be above patient's designated goal

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

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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) <u>Initiation (new start) criteria in pediatric patients for obesity</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 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 95th 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)

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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:
   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)

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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:
   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

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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 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 (Victoza)
   - Note: If patient is currently on liraglutide (Victoza), must meet the additional DM2 criteria

-OR-

11) Adults (age 20+) with a 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. On maximally tolerated metformin dose or intolerance or contraindication to metformin XR
   ii. On maximally tolerated sulfonylurea or has contraindication/intolerance to sulfonylureas
   iii. On pioglitazone or has contraindication/intolerance to pioglitazone
   iv. On an SGLT2 inhibitor (e.g. Jardiance) or has contraindication/intolerance to SGLT2 inhibitors
   v. HbA1c or GMI is at or within 2% of patient's designated goal

-OR-

c) Patient is on (or history of) insulin at a total daily dose of ≥ 0.5 units/kg/day, meet ALL of the following criteria:
   i. On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR

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ii. On an SGLT2 inhibitor (e.g. Jardiance) or pioglitazone or has contraindication/intolerance to both

-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 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 (i.e. Jardiance) AND liraglutide (Victoza)
    - Note: If patient is currently on an SGLT-2 inhibitor and/or liraglutide (Victoza), 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 or within 2% of patient's designated goal if not on insulin

-OR-

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)

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16) **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)

17) **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