

Criteria-Based Consultation Prescribing Program Kaiser Permanente Northwest Region CRITERIA FOR DRUG COVERAGE

liraglutide (Victoza)

Notes:

- Quantity Limits: Yes
- GMI = Glucose Management Indicator, an estimated A1c level based on continuous glucose monitoring data
- * 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

Initiation (new start) criteria in patients for Type 2 Diabetes Mellitus: Formulary **liraglutide (Victoza)** will be covered on the prescription drug benefit 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 Multi 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 an SGLT-2 inhibitor (e.g. Jardiance)
 - Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria

-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)

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- 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. 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 intolerance* or contraindication to metformin XR
 - ii. HbA1c or GMI is above patient's designated goal

-OR-

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)
 - Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria

-OR-

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4) Members aged 10-19 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 is above, but within 2% of, patient's designated goal[#]
 - If patient on insulin, A1c only needs to be above patient's designated goal

-OR-

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

Formulary **liraglutide (Victoza)** 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 Multiple 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 are documented in the encounter in which liraglutide (Victoza) is ordered; AND
- f) Patient is currently following a diet and exercise program; AND
- g) 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 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

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

-AND-

- i) Patient has then failed an adequate trial or has an allergy, intolerance, or contraindication to semaglutide (Ozempic/Wegovy)

6) Initiation (new starts) criteria for pediatric patients for obesity: Non-formulary **liraglutide (Victoza)** 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 are documented within the last month from the date in which liraglutide (Victoza) is ordered; AND
- f) Patient is currently following a diet and exercise program; AND
- g) BMI greater than or equal to 35 kg/m² or great than or equal to 120% of the 95th percentile

-AND-

- h) Patient has failed an adequate trial[^] to at least two of the following medication 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)

-AND-

- h) Patient has then failed an adequate trial or has an allergy, intolerance, or contraindication to semaglutide (Ozempic/Wegovy)

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Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **liraglutide (Victoza)** will be covered on the prescription drug benefit for when the following criteria are met:

7) 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 an SGLT-2 inhibitor
 - Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria

-OR-

8) 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 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. Most recent 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, meets the following criteria:
 - i. On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR

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-OR-

9) 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)
 - Note: If patient is currently on an SGLT-2 inhibitor, must meet the additional DM2 criteria

-OR-

10) Members aged 10-19 years 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) 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-

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

12) Continued use criteria (every 12 months) for patients previously reviewed and approved when used for chronic weight management/obesity: Non-formulary **liraglutide (Victoza)** 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 liraglutide (Victoza)

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