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Coverage Po	olicy/Guideline			
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#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Liraglutide, Ozempic, Segluromet, and Steglatro under the patient's prescription drug benefit.

## **Description:**

## Ozempic

# **FDA-approved Indications**

Ozempic is 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, nonfatal myocardial infarction, or non-fatal stroke) 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

# **Segluromet**

## **FDA-approved Indications**

Segluromet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use:

Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus

## **Steglatro**

#### **FDA-approved Indications**

Steglatro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use:

Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

#### Victoza

## **FDA-approved Indications**

Liraglutide is indicated:

• as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.

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• 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 and established cardiovascular disease.

## Limitations of Use:

- Liraglutide should not be used in patients with type 1 diabetes mellitus.
- Liraglutide contains liraglutide and should not be co-administered with other liraglutide-containing products.

## Compendial Uses:

Advanced chronic kidney disease (CKD) in adults with type 2 diabetes mellitus

## **Applicable Drug List:**

# Formulary with Step Therapy:

Liraglutide Ozempic Segluromet Steglatro

## **Policy/Guideline:**

#### **Coverage Criteria**

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months when ALL of the following criteria are met:

- If the request is for a Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists [Note: Examples of GLP-1 Agonists are liraglutide and Ozempic.], then ONE of the following criteria is met:
  - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
    - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL.

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- The patient meets ONE of the following criteria:
  - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to metformin.
  - o The patient requires combination therapy AND has an A1C of 7.5 percent or greater.
  - o The patient has established cardiovascular disease, and the following criteria is met:
    - The request is for Ozempic or liraglutide.
  - The patient has a diagnosis of chronic kidney disease AND the following criteria is met:
    - The request is for Ozempic.
  - The patient has a diagnosis of advanced chronic kidney disease (CKD) (estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73m2) and the following criteria is met:
    - The request is for liraglutide.

## **Continuation of Therapy**

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the patient has been receiving a stable maintenance dose of the requested drug for at least 3 months when ALL of the following criteria are met:

- If the request is for a Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists [Note: Examples of GLP-1 Agonists are liraglutide and Ozempic.], then ONE of the following criteria is met:
  - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
    - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient meets ONE of the following criteria:
  - The patient has demonstrated a reduction in A1C since starting this therapy.
  - o The patient has established cardiovascular disease, and the following criteria is met:
    - The request is for Ozempic or liraglutide
  - The patient has a diagnosis of chronic kidney disease, and the following criteria is met:

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- The request is for Ozempic.
- The patient has a diagnosis of advanced chronic kidney disease (CKD) (estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73m2) and the following criteria is met:
  - The request is for liraglutide.

# **Approval Duration and Quantity Restrictions:**

**Initial and Renewal Approval: 12 months** 

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

#### **References:**

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- 2. Segluromet [package insert]. Rahway, NJ: Merck Sharpe & Dohme LLC.; September 2023.
- 3. Steglatro [package insert]. Rahway, NJ: Merck Sharpe & Dohme LLC.; September 2023.
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