Prior Authorization Criteria

Kentucky Medicaid

WEGOVY (SEMAGLUTIDE)

Approval Duration: 6 months

Quantity Limit:

- Pen injector: 4 pens per 28 days
- Tablet: 1 tablet per day

1. INITIAL APPROVAL CRITERIA

For Major Adverse Cardiovascular Events (MACE) risk reduction:

- Patient age ≥ 45 years; **AND**
- Being prescribed for MACE risk reduction (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke); **AND**
- Prescriber includes documentation (e.g., progress note) within the past year of pre-existing cardiovascular (CV) disease as defined by ≥ 1 of the following:
    - Previous myocardial infarction (MI); **OR**
    - Previous stroke (ischemic or hemorrhagic); **OR**
    - Symptomatic peripheral arterial disease:
        - Amputation due to atherosclerotic disease;
        - History of peripheral arterial revascularization procedure;
        - Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest); **AND**
- Prescriber includes documentation (e.g., progress note) AND the patient has a claims history showing optimization on specified lipid-lowering therapy (e.g., moderate to high intensity statin, PCSK9) AND ≥ 1 of the following:
    - Beta-blocker; **OR**
    - RAS inhibitor such as an angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI); **OR**
    - Antiplatelet (e.g., aspirin, clopidogrel); **OR**
    - Prescriber has provided medical justification as to why the patient cannot use lipid-lowering therapies AND beta-blockers, RAS inhibitors, or antiplatelet therapies (provider must include dates of trial, if applicable); **AND**
- Patient has a body-mass index (BMI) of 27 kg/m^2 or greater; **AND**
- Prescriber includes documentation that the medication will be used in combination with a reduced calorie diet and increased physical activity; **AND**

- Patient does not have any of the following:
  - A history of type 2 diabetes;
  - Current A1c of 6.5% or higher;
  - New York Heart Association (NYHA) class IV heart failure;
  - End-stage kidney disease or dialysis;
  - Plans to undergo coronary, carotid, or peripheral revascularization;
  - No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2);
  - Female who is pregnant, breast-feeding or intends to become pregnant or is of child-bearing potential and not using a highly effective contraceptive method; **AND**
- The requested dose does not exceed the maximum FDA-approved dose; **AND**
- Not used in combination with another glucagon-like peptide (GLP-1) OR dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist.

For Metabolic Dysfunction-Associated Steatohepatitis (MASH):

- The request is not for Wegovy tablet; **AND**
- Patient age ≥ 18 years; **AND**
- Diagnosis of Metabolic Dysfunction-Associated Steatohepatitis (MASH), also known as Nonalcoholic Steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), confirmed by one of the following:
  - Liver biopsy within the last 3 years; **OR**
  - Fibrosis-4 (FIB-4) index of > 2.67 within the last 6 months; **OR**
  - FIB-4 index of 1.3 to 2.67 with sequential vibration-controlled transient elastography (VCTE) or enhanced liver fibrosis test (ELF) within the last 6 months; **AND**
- Patient does not have any of the following:
  - A history of type 2 diabetes
  - Evidence of cirrhosis;
  - Hepatic decompensation;
  - Hepatocellular carcinoma (HCC);
  - Female who is pregnant, breast-feeding or intends to become pregnant or is of child-bearing potential and not using a highly effective contraceptive method; **AND**

- Patient has had a trial of diet, exercise and lifestyle modification and will continue these if the medication is approved.; **AND**
- Prescribed by, or in consultation with, a gastroenterologist or hepatologist; **AND**
- Prescriber attests that member does not have excessive alcohol consumption; **AND**
- The requested dose does not exceed the maximum FDA-approved dose.; **AND**
- Not used in combination with another GLP-1 or dual GLP-1/GIP receptor agonist.

2. RENEWAL CRITERIA

For Major Adverse Cardiovascular Events (MACE) risk reduction:

- Patient has not experienced any serious adverse effects, including development of pancreatitis; **AND**
- Patient does not have any of the following:
  - A history of type 2 diabetes;
  - Current A1c of 6.5% or higher;
  - New York Heart Association (NYHA) class IV heart failure;
  - End-stage kidney disease or dialysis;
  - Plans to undergo coronary, carotid, or peripheral revascularization;
  - No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2);
  - Female who is pregnant, breast-feeding or intends to become pregnant or is of child-bearing potential and not using a highly effective contraceptive method; **AND**
- Patient continues to use in combination with a reduced calorie diet and increased physical activity; **AND**
  - Prescriber verifies and includes documentation that patient has at least 5% reduction in baseline body weight; **OR**
  - Provider includes documentation assessing lifestyle and diet interventions if weight loss goal has not been met; **AND**
- Patient continues to use in concomitant therapy with cardiovascular disease therapy management; **AND**
- The requested dose does not exceed the maximum FDA-approved dose; **AND**
- Not used in combination with another GLP-1 or dual GLP-1/GIP receptor agonist.

For Metabolic Dysfunction-Associated Steatohepatitis (MASH):

- Prescriber submits clinical documentation that the patient has experienced a clinical benefit compared to baseline, confirmed by ≥ 1 of the following:

- Liver biopsy improvement; **OR**
- Reduction in steatohepatitis, defined by a reduction in the total nonalcoholic fatty liver disease activity score (NAS); **OR**
- Reduction in liver fibrosis, defined by a reduction in the Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN) fibrosis scale; **OR**
- Reduction in steatosis; **OR**
- Reduction in lobular inflammation; **OR**
- Reduction in ballooning; **AND**

- Patient will continue lifestyle modifications, including a reduced calorie diet and increased physical activity plan.; **AND**
- Patient has not experienced any serious adverse effects, including development of pancreatitis; **AND**
- Patient does not have any of the following:
  - A history of type 2 diabetes
  - Evidence of cirrhosis;
  - Hepatic decompensation;
  - Hepatocellular carcinoma (HCC);
  - Female who is pregnant, breast-feeding or intends to become pregnant or is of child-bearing potential and not using a highly effective contraceptive method; **AND**
- The requested dose does not exceed the maximum FDA-approved dose; **AND**
- Not used in combination with another GLP-1 or dual GLP-1/GIP receptor agonist.