curative

GLP-1/GIP Expanded Indications Prior Authorization

Drug(s) Applied:	**Wegovy** (semaglutide)

No Weight Loss Program/ <u>Standard</u> Weight Loss Programs (Weight Loss No-Copay / Weight Loss Split Cost) Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
   - **A. Reduce the risk of Major Adverse Cardiovascular Event (MACE),** as indicated by chart notes within past 3 months
     1. Patient is 45 years of age or older **and**
     2. Requested agent is to reduce the risk of MACE (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) **and**
     3. Patient has established cardiovascular disease and a history of ONE of the following: (medical records required)
        a) Myocardial infarction
        b) Stroke
        c) Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **and**
     4. BMI greater than or equal to 27 kg/m^2 **and**
     5. Patient does NOT have type 2 diabetes **and**
     6. Patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) or is being managed for tobacco cessation **and**
     7. Chart notes and/or prescriber provide documentation that patient is being treated with the standard of care for concomitant comorbid conditions (e.g. antihypertensive therapy (e.g. ACE Inhibitor, angiotensin receptor blocker, beta blocker), lipid lowering therapy (e.g. statin, ezetimibe) **and**
     8. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another GLP-1 receptor agonist **and**
     9. Chart notes and/or prescriber do not provide documentation that patient has any FDA labeled contraindications (e.g. personal or family history of medullary

thyroid carcinoma (MTC); patient has multiple endocrine neoplasia syndrome type 2 (MEN2)) **and**

10. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., cardiology)

Approval Duration: 12 months

B. **Metabolic Dysfunction-Associated Steatohepatitis (MASH)** as indicated by chart notes within past 3 months
   1. Patient is 18 years of age or older **and**
   2. Requested agent is for treatment of MASH with moderate to advanced liver fibrosis, consistent with stages F2 to F3 fibrosis after at least 6 months with maximally tolerated dose of pioglitazone **and**
   3. Diagnosis and fibrosis staging confirmed by one of the following: biopsy; magnetic resonance elastography (MRE); vibration-controlled transient elastography (VTCE) within the past 365 days **and**
   4. Patient will be using requested agent with concurrent pioglitazone therapy or chart notes document contraindication to pioglitazone **and**
   5. Chart notes and/or prescriber provide documentation that patient has concomitant metabolic comorbidities (e.g. hypertriglyceridemia, central obesity) **and**
   6. Chart notes and/or prescriber provide documentation that patient will be using the requested medication with lifestyle modifications such as diet and exercise **and**
   7. Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterology, hepatology)

Approval Duration: 12 months

II. Continued Therapy Criteria

A. Reduce the risk of Major Adverse Cardiovascular Event (MACE) as indicated by chart notes within past 12 months
   1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
   2. If for Wegovy, requested dose is 1.7mg or 2.4mg **and**
   3. Documented clinical benefit since starting the requested agent **and**
   4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another GLP-1 receptor agonist **and**
   5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., cardiology)

Approval Duration: 12 months

B. **Metabolic Dysfunction-Associated Steatohepatitis (MASH)** as indicated by chart notes within past 12 months
   1. Patient meets the initial therapy criteria above **and**
   2. If for Wegovy, requested dose is 1.7mg or 2.4mg **and**
   3. Documented clinical benefit (e.g. improvement of liver fibrosis or no worsening of steatohepatitis) since starting the requested agent **and**
   4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another GLP-1 receptor agonist **and**
   5. Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterology, hepatology)

   Approval Duration: 12 months

Flex Weight Loss Programs (Weight Loss No-Copay / Weight Loss Split Cost) Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

III. Initial Therapy Criteria

A. Reduce the risk of Major Adverse cardiovascular event (MACE) as indicated by chart notes within past 3 months
   1. Patient is 18 years of age or older **and**
   2. Requested agent is to reduce the risk of MACE (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) **and**
   3. Patient has established cardiovascular disease and history of ONE of the following: (medical records required)
      a) Myocardial infarction
      b) Stroke
      c) Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **and**
   4. BMI greater than or equal to 27 kg/m^2 **and**
   5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another GLP-1 receptor agonist **and**
   6. Chart notes and/or prescriber do not provide documentation that patient has

any FDA labeled contraindications (e.g. personal or family history of medullary thyroid carcinoma (MTC); patient has multiple endocrine neoplasia syndrome type 2 (MEN2))

Approval Duration: 12 months

B. Metabolic Dysfunction-Associated Steatohepatitis (MASH) as indicated by chart notes within past 3 months

1. Patient is 18 years of age or older **and**
2. Requested agent is for treatment of MASH with moderate to advanced liver fibrosis, consistent with stages F2 to F3 fibrosis **and**
3. Diagnosis and fibrosis staging confirmed by one of the following: biopsy; magnetic resonance elastography (MRE); vibration-controlled transient elastography (VTCE) **and**
4. Chart notes and/or prescriber provide documentation that patient has concomitant metabolic comorbidities (e.g. hypertriglyceridemia, central obesity) **and**
5. Chart notes and/or prescriber provide documentation that patient will be using the requested medication with lifestyle modifications such as diet and exercise

Approval Duration: 12 months

IV. Continued Therapy Criteria

A. Reduce the risk of Major Adverse Cardiovascular Event (MACE) as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent

Approval Duration: 12 months

B. Metabolic Dysfunction-Associated Steatohepatitis (MASH) as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Documented clinical benefit (e.g. improvement of liver fibrosis or no worsening of steatohepatitis) since starting the requested agent

Approval Duration: 12 months

Policy Owned by: Curative PBM team