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Scope: Medicaid

GLP-1 Agonists and GIP/GLP-1 Agonists

GLP-1 Agonists Drug Name: Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide)

GIP/GLP-1 Agonists Drug Name: Mounjaro (tirzepatide)

I. CRITERIA FOR APPROVAL

An authorization of 12 months may be granted when all the following criteria are met:

Diabetes:

- A. Patient has a documented diagnosis of type 2 diabetes mellitus confirmed by accepted laboratory testing methodologies per treatment guidelines (e.g., A1C greater than or equal to 6.5%, fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL or a random plasma glucose greater than or equal to 200 mg/dL); AND
- B. Patient has not achieved target glucose control using a maximum tolerated dose of metformin (2 grams/day) for 3 months unless metformin monotherapy is not clinically appropriate in the patient (i.e., A1C is greater than or equal to 9% or metformin is contraindicated)
- C. For Mounjaro requests, the patient has experienced an inadequate treatment response, intolerance, or contraindication to Ozempic OR Rybelsus; AND
- D. For Ozempic, Rybelsus, and Mounjaro requests, the patient is 18 years of age or older; OR
- E. For Trulicity requests the patient is 10 years of age and older; AND
- F. For Trulicity requests for patients 18 years of age and older, they have experienced an inadequate treatment response, intolerance, or contraindication to Ozempic OR Rybelsus
- G. Ozempic, Rybelsus, Trulicity, and Mounjaro will not be used in conjunction with a Dipeptidyl Peptidase-4 (DPP-4) Inhibitors (Alogliptin, Alogliptin-metformin, Alogliptin-pioglitazone)

Type 2 diabetes with cardiovascular disease, cardiovascular risk factors or chronic kidney disease:

- A. The patient is 18 years of age and older;
- B. Patient has a documented diagnosis of type 2 diabetes mellitus confirmed by accepted laboratory testing methodologies per treatment guidelines (e.g., A1C greater than or equal to 6.5%, fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL or a random plasma glucose greater than or equal to 200 mg/dL); AND
- C. The patient meets one of the following:
 - a. The request is for Ozempic or Trulicity and the patient has established cardiovascular disease with a history of ONE of the following:

- i. Previous myocardial infarction (MI)
 - ii. Previous stroke
 - iii. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease
 - iv. Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty)
 - b. The request is for Ozempic and the patient has a diagnosis of chronic kidney disease
 - c. The request is for Trulicity and the patient has a diagnosis of an advanced chronic kidney disease (CKD) with an eGFR less than 30mL/min/1.73m²
 - d. The request is for Trulicity and the patient has multiple cardiovascular risk factors
- D. For Trulicity requests in patients over 18 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or contraindication to Ozempic

II. CONTINUATION OF THERAPY

Type 2 Diabetes:

A continuation of therapy authorization of 12 months may be granted for patients with type 2 diabetes when ALL the following are met:

- i. Documentation demonstrating a reduction in A1C since starting therapy; **AND**
- ii. Documentation that the patient meets ALL initial criteria.

Type 2 diabetes with cardiovascular disease, cardiovascular risk factors or chronic kidney disease:

An authorization of 12 months may be granted when all patients with type 2 diabetes with cardiovascular disease, cardiovascular risk factors or chronic kidney disease are requesting authorization for continuation of therapy with documentation that they meet ALL initial criteria.

III. QUANTITY LIMIT

Ozempic 2/1.5ml, Ozempic 4/3ml, Ozempic 8/3ml: 1 pen per 28 days

Trulicity 0.75/0.5ml, 1.5/0.5ml, 3/0.5ml, 4.5/0.5ml: 4 pens per 28 days

Rybelsus 1.5 mg (formulation R2) and 3 mg (formulation R1): 30 tabs every 180 days

Rybelsus 7mg & 14mg (formulation R1): 1 tablet per day

Rybelsus 4mg & 9mg (formulation R2): 1 tablet per day

Mounjaro 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg per 0.5 mL: 4 pens (2 mL) per 28 days