Mounjaro (tirzepatide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Mounjaro (tirzepatide)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mounjaro (tirzepatide) may be approved when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of type 2 diabetes; **AND**
III. Documentation is provided that diagnosis has been verified by history of:
   A. Hemoglobin A1c (A1C) greater than or equal to 6.5%; **OR**
   B. Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL (after fasting for at least 8 hours); **OR**
   C. 2 hour plasma glucose greater than or equal to 200 mg/dL as part of an oral glucose tolerance test (75 g oral glucose after fasting for at least 8 hours); **OR**
   D. Symptoms of hyperglycemia (including polyuria, polydipsia, polyphagia) and a random plasma glucose greater than or equal to 200 mg/dL;

AND

IV. Individual has had a trial and inadequate response or intolerance to metformin (AACE 2023). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
OR
V. Individual has a contraindication to metformin therapy;

AND
VI. Documentation is provided that individual has had a trial and inadequate response or intolerance to two preferred GLP-1 receptor agonists. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

Preferred GLP-1 receptor agonists agents: Ozempic, Trulicity, Victoza.

Requests for Mounjaro (tirzepatide) may not be approved for the following:

I. Individual with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) or a personal or family history of medullary thyroid carcinoma (MTC); **OR**
II. Individual is requesting for treatment of type 1 diabetes; **OR**
III. Individual is requesting for the treatment of prediabetes; **OR**
IV. Individual is requesting for the treatment of obesity; **OR**
V. Individual is requesting for weight loss; **OR**
VI. Individual is using in combination with a GLP-1 receptor agonist (including but not limited to Saxenda, Wegovy, Adlyxin, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity, Victoza, Soliqua or Xultophy); **OR**
VII. Individual is using in combination with a DPP4 inhibitor (including but not limited to Janumet/XR, Januvia, Jentadueto/XR, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, Tradjenta, Glyxambi, Qtern, Steglujan or Trijardy XR).

Note:
Mounjaro has a black box warning for risk of thyroid C-cell tumors. GLP-1 receptor agonists have been found to cause thyroid C-cell tumors at clinically relevant exposure in rats. It is unknown whether GLP-1 receptor agonists cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. Mounjaro is contraindicated in individuals with a personal or family history of MTC or in individuals with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Individuals using GLP-1 receptor agonists should be educated on the potential risk of MTC and symptoms of thyroid tumors.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 8, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Garber AJ, Handelsman Y, Grunberger G, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) on the Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary. *Endocrine Practice*. 2020;26:107-139.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. US Food and Drug Administration. FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. Last updated: November 14, 2017. Available at https://www.fda.gov/Drugs/DrugSafety/ucm493244.htm. Accessed: April 14, 2022.