

**Subject: GIP-GLP-1 Agonist Mounjaro PA with Limit Policy 5468-C UDR 05-2024**

**Drug**

GLUCOSE-DEPENDENT INSULINOTROPIC POLYPEPTIDE (GIP)/GLUCAGON-LIKE PEPTIDE 1 (GLP-1) RECEPTOR AGONIST

**MOUNJARO** (*tirzepatide*)

**Policy:**

**FDA-APPROVED INDICATIONS**

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

**Limitations of Use**

- Mounjaro has not been studied in patients with a history of pancreatitis.
- Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.

**COVERAGE CRITERIA**

**Type 2 Diabetes Mellitus**

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months and ONE of the following criteria are met:
  - The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
  - The patient requires combination therapy AND has an A1C of 7.5 percent or greater

**CONTINUATION OF THERAPY**

**Type 2 Diabetes Mellitus**

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months
- The patient has demonstrated a reduction in A1C since starting this therapy

**QUANTITY LIMITS APPLY**

4 single-dose pens or single-dose vials (2 mL) per 21 days\* OR 12 single-dose pens or single-dose vials (6 mL) per 63 days\*

*\*The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.*

**DURATION OF APPROVAL (DOA)**

- 5467-C: DOA: 12 months
- 5468-C: DOA: 36 months

**Place of Service:**

Outpatient

**The above policy is based on the following references:**

1. Mounjaro [package insert]. Indianapolis, IN: Lilly USA, LLC; July 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed March 11, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 03/11/2024).
4. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. *Endocr Pract.* 2022;28(10):923-1049.
5. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care.* 2022;45(11):2753-2786.

6. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – *Diabetes Care*. 2024;47(Suppl. 1):S1-S322.
7. Samson SL, Vellank P, Blonde L, et. Al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. *Endocr Pract*. 2023; 29: 305-340.

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