

## PRIOR AUTHORIZATION POLICY

**POLICY:** Diabetes – Mounjaro Prior Authorization Policy

- Mounjaro™ (tirzepatide subcutaneous injection – Lilly)

**REVIEW DATE:** 06/07/2023; selected revision 07/05/2023

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### OVERVIEW

Mounjaro, a glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) agonist, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**.

### Guidelines

According to the American Diabetes Association Standards of Care (2023), regarding pharmacologic therapy for adults with type 2 diabetes, a patient-centered approach should guide the choice of agents.<sup>2</sup> Consider the effects on cardiovascular and renal comorbidities, efficacy, hypoglycemia risk, impact on weight, risk for adverse events (AEs), and patient preferences. Of note, for patients with type 2 diabetes, a GLP-1 agonist is preferred over insulin when possible. Further, if insulin is used, combination therapy with a GLP-1 agonist is recommended for greater efficacy, durability of treatment effect, and weight and hypoglycemia benefit. The very high glycemic efficacy of the GLP-1 agonists (cited as semaglutide and Trulicity® [dulaglutide injection]) and Mounjaro are recognized. The American Association of Clinical Endocrinologists provide similar recommendations.<sup>3,4</sup>

An American College of Cardiology Consensus Pathway on the management of heart failure with preserved ejection fraction (HFpEF) cites substantial weight loss with Mounjaro and semaglutide in patients with type 2 diabetes and obesity and notes promising data with Mounjaro as well as other GLP-1 agonists based on their weight loss potential.<sup>5</sup> Although the findings are encouraging, neither product has been rigorously studied in patients with heart failure, and concerns over loss of lean muscle mass in patients with heart failure are noted. Ongoing studies with each product will provide more information in patients with HFpEF.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Mounjaro. All approvals are provided for the duration noted below.

**Automation:** If criteria for a previous use of an oral medication for diabetes (not including Rybelsus® [semaglutide tablets] or single-entity metformin) in the past 130 days are not met at the point of service, OR if the patient is < 18 years of age, coverage will be determined by Prior Authorization criteria.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mounjaro is recommended in those who meet the following criteria:

#### FDA-Approved Indication

1. **Type 2 Diabetes Mellitus.** Approve for 1 year if the patient is  $\geq 18$  years of age.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

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Coverage of Mounjaro is not recommended in the following situations:

- 1. Weight Loss.** Mounjaro is not FDA-approved for weight loss in a patient who is overweight (body mass index [BMI]  $\geq 27$  kg/m<sup>2</sup>) or obese (BMI  $\geq 30$  kg/m<sup>2</sup>) without type 2 diabetes. Clinical trials in a patient who is overweight or obese are ongoing. Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.
- 2. Type 1 Diabetes Mellitus.** Mounjaro is not indicated for type 1 diabetes. Clinical trials excluded patients with type 1 diabetes.
- 3. Prediabetes/Diabetes Prevention.** Mounjaro is not indicated in a patient with elevated blood glucose who does not have type 2 diabetes. The American Diabetes Association Standards of Care (2023) state that metformin therapy should be considered in adults at high-risk of diabetes.<sup>2</sup> Further, the standards note that metformin has the longest of safety data as a pharmacologic therapy for diabetes prevention. Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.
- 4. Metabolic Syndrome.** Mounjaro is not indicated in a patient with metabolic syndrome who does not have type 2 diabetes. Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.
- 5.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Mounjaro™ subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; May 2022.
2. American Diabetes Association. Standards of medical care in diabetes – 2023. *Diabetes Care*. 2023;46(Suppl 1):S1-S291.
3. 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;18:923-1049.
4. Samson SL, Vellanki 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.
5. Kittleson MM, Panjath GS, Amancherla K, et al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction. *JACC*. 2023;81(18):1835-1878.