VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Diabetes – Mounjaro Prior Authorization Policy
- Mounjaro™ (tirzepatide subcutaneous injection – Lilly)

REVIEW DATE: 06/01/2022; selected revision 09/21/2022 and 03/01/2023

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
Mounjaro is not yet addressed in guidelines. According to the American Diabetes Association Standards of Care (2022), regarding pharmacologic therapy for adults with type 2 diabetes, a patient-centered approach should guide the choice of agents.[2] Consider the effects on cardiovascular and renal comorbidities, efficacy, hypoglycemia risk, impact on weight, risk for AEs, and patient preferences. Of note, for patients with type 2 diabetes, a GLP-1 agonist is preferred over insulin when possible.

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 ≥ 18 years of age.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Mounjaro is not recommended in the following situations:

1. **Weight Loss.** Mounjaro is not FDA approved for weight loss in a patient without type 2 diabetes. Clinical trials in patients with overweight or obesity 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, and these patients were excluded from clinical trials.

3. **Prediabetes/Diabetes Prevention.** Mounjaro is not indicated in this setting.

4. 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 – 2022. *Diabetes Care.* 2022;45(Suppl 1):S1-S258.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/01/2022
Selected Revision	**Automation:** Automation was added to the policy such that if a patient has a claim for one oral medication for diabetes (not including Rybelsus® [semaglutide tablets]) within a 130-day lookback period AND the patient is ≥ 18 years of age, the claim will adjudicate. **Conditions Not Recommended for Approval:** The condition of "Prediabetes/Diabetes Prevention" was added to Conditions Not Recommended for Approval.	09/21/2022
Selected Revision	Automation: Automation was updated to remove single-entity metformin as an oral medication that has been used for diabetes in the past 130 days. Previously, Rybelsus was the only oral agent not included in this automation.	03/01/2023