PRIOR AUTHORIZATION POLICY

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

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

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.[2] 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 recommendaitons.[3,4]

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.[5] 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.

Mounjaro™ (tirzepatide subcutaneous injection (Lilly)
is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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

CONDITIONS NOT COVERED

Mounjaro™ (tirzepatide subcutaneous injection (Lilly)
is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Weight Loss.** Mounjaro is not FDA-approved for weight loss in a patient who is overweight (body mass index [BMI] ≥ 27 kg/m^2) or obese (BMI ≥ 30 kg/m^2) 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.[2] Further, the standards note that metformin has the longest history 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.** Monjauro 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.

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, Panjrath 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.

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 Covered** **:** The condition of "Prediabetes/Diabetes Prevention" was added to Conditions Not Covered .	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
Annual Revision	No criteria changes.	06/07/2023
Selected revision	**Conditions Not Covered** **:** **Metabolic Syndrome** in was added to Conditions Not Covered ; this applies to patients without a diagnosis of type 2 diabetes.	07/05/2023