BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

MOUNJARO™ (tirzepatide) subcutaneous injection

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Mounjaro (tirzepatide) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

  2. Individual is 18 years of age or older

  3. Individual has a confirmed diagnosis of type 2 diabetes mellitus used as an adjunct to diet and exercise to improve *glycemic* control

  4. The individual is on a diet and exercise program targeted to improve *glycemic* control and **not** for weight management

5. Hemoglobin A1C is 8% or more

6. The individual does **NOT** have any of the following:
    a. Type 1 diabetes mellitus
    b. History of pancreatitis
    c. Acute gallbladder disease such as cholelithiasis, cholecystitis, or biliary colic
    d. Severe gastrointestinal disease such as severe gastroparesis
    e. Non-proliferative diabetic retinopathy requiring acute therapy
    f. Proliferative diabetic retinopathy
    g. Diabetic macular edema

7. Documented failure (at least a 6 month trial of each), contraindication per FDA label, intolerance, or not a candidate to **ONE** agent in **EACH** of the following categories:
    a. Biguanide: Metformin
    b. **ONE** sodium-glucose co-transporter 2 (SGLT-2) inhibitor:
        i. Invokana (canagliflozin)
        ii. Farxiga (dapagliflozin)
        iii. Jardiance (empagliflozin)
        iv. Steglatro (ertugliflozin)
    c. **ONE** glucagon-like peptide 1 receptor (GLP-1) agonists:
        i. Trulicity (dulaglutide)
        ii. Exenatide (Byetta, Bydureon, or Bydureon BCise)
        iii. Victoza (liraglutide) [Note: **NOT** Saxendra (liraglutide)]
        iv. Adlyxin (lixisenatide)
        v. Semaglutide (Ozempic or Rybelsus) [Note: **NOT** Wegovy (semaglutide)]

8. There are **NO** FDA-label contraindications, such as:
    a. Personal or family history of medullary thyroid carcinoma (MTC)
    b. Individual with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Mounjaro (tirzepatide) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

2. Individual's condition has responded while on therapy with response defined as:
    a. Achieved and maintains HgA1C at less than 7%
    b. No evidence of disease progression

3. Individual has been adherent with the medication

4. Individual is on a diet and exercise program targeted to improve *glycemic* control

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Pancreatitis
        ii. Severe hypersensitivity reaction
        iii. Acute kidney injury
        iv. Gastrointestinal reaction such as severe nausea, vomiting, diarrhea, or dehydration
        v. Cholelithiasis, cholecystitis, or biliary colic

6. The individual does **NOT** have any of the following:
    a. Type 1 diabetes mellitus
    b. Severe gastrointestinal disease such as severe gastroparesis
    c. Non-proliferative diabetic retinopathy requiring acute therapy
    d. Proliferative diabetic retinopathy
    e. Diabetic macular edema

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

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

Tirzepatide selectively binds to and activates both the GIP and GLP-1 receptors, the targets for native GIP and GLP-1. Tirzepatide enhances first- and second-phase insulin secretion, and reduces glucagon levels, both in a glucose dependent manner. Tirzepatide lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes mellitus.

Tirzepatide increases insulin sensitivity, reduces fasting and postprandial glucagon concentrations, and delays gastric emptying. The delay is largest after the first dose and this effect diminishes over time. Tirzepatide slows post-meal glucose absorption, reducing postprandial glucose.

Resources:

Mounjaro (tirzepatide) product information, revised by Eli Lilly and Company 05-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 01, 2022.