BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

MOUNJARO™ (tirzepatide) subcutaneous injection Generic Equivalent (if available)

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 prior authorization 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) and/or generic equivalent (if available) are 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 (requested medication is **not** solely being used for weight loss)

4. Individual is on a diet and exercise program targeted to improve *glycemic* control and for weight management and is on a diabetes medical regimen to control hyperglycemia

5. Hemoglobin A1C is 7% or more

6. 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. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Individual has documented failure (at least a 6-month trial of each), contraindication per FDA label, intolerance, or is not a candidate for **ONE** agent in **EACH** of the following categories:
    a. Biguanide: Metformin
    b. Glucagon-like peptide 1 receptor (GLP-1) agonists (e.g., Trulicity (dulaglutide), Victoza (liraglutide), semaglutide (Ozempic or Rybelsus)) [Note: **NOT** Saxenda (liraglutide), Wegovy (semaglutide)]
    c. Sodium-glucose co-transporter 2 (SGLT-2) inhibitor (e.g., Farxiga (dapagliflozin), Jardiance (empagliflozin))

9. 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
- Individual may be referred to case management for diabetes related ancillary services

- **Criteria for continuation of coverage (renewal request):** Mounjaro (tirzepatide) and/or generic equivalent (if available) are 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 has a confirmed diagnosis of type 2 diabetes mellitus

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

4. Individual has been adherent with the medication

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual is on a diet and exercise program targeted to improve *glycemic* control and continues a diabetes medical regimen to control hyperglycemia

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

8. 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.

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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.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Mounjaro (tirzepatide) product information, revised by Eli Lilly and Company 07-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 31, 2024.

Wexler DJ. Initial management of hyperglycemia in adults with type 2 diabetes mellitus. In: UpToDate, Nathan DM, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated March 18, 2024. Accessed July 12, 2024.

Wexler DJ. Management of persistent hyperglycemia in type 2 diabetes mellitus. In: UpToDate, Nathan DM, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated May 22, 2024. Accessed July 12, 2024.

Dungan K, DeSantis A. Glucagon-like peptide 1-based therapies for the treatment of type 2 diabetes mellitus. In: UpToDate, Nathan DM, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated June 07, 2024. Accessed July 12, 2024.

DeSantis A. Sodium-glucose cotransporter 2 inhibitors for the treatment of hyperglycemia in type 2 diabetes mellitus. In: UpToDate, Nathan DM, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through June 2024. Topic last updated June 04, 2024. Accessed July 12, 2024.

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