DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Diabetes – Mounjaro Drug Quantity Management Policy – Per Days
- Mounjaro® (tirzepatide subcutaneous injection – Eli Lilly)

REVIEW DATE: 10/30/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 glucagon-like peptide-1 (GLP-1)/glucose-dependent insulinotropic polypeptide-1 (GIP) agonist, is indicated as an adjunct to diet and exercise to improve glycemic control in **adults with type 2 diabetes mellitus**.[1]

Dosing

The recommended initial dose of Mounjaro is 2.5 mg administered subcutaneous (SC) once weekly (QW).[1] The 2.5 mg dose is not intended for glycemic control, but is to be used for treatment initiation only. After 4 weeks, the Mounjaro dose should be increased to 5 mg SC QW. If additional glycemic control is needed, the dose should be increased in 2.5 mg increments after ≥ 4 weeks on the current dose. The maximum dose of Mounjaro is 15 mg SC QW. If a dose is missed, the next dose should be administered as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, the missed dose should be skipped and Mounjaro administered on the next regularly scheduled day. In either case, then the regular QW dosing schedule should be resumed. The administration day may be changed, if needed, as long as at least 3 days (72 hours) passes between doses.

Availability

Mounjaro is supplied as single-dose pens in cartons containing four pens each. The pens are available in the following strengths:[1]

- 2.5 mg/0.5 mL pen
- 5 mg/0.5 mL pen
- 7.5 mg/0.5 mL pen
- 10 mg/0.5 mg pen
- 12.5 mg/0.5 mL pen
- 15 mg/0.5 mL pen

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Mounjaro. There are no overrides to the Per Days quantity limits outlined below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity Per 28 Days	Home Delivery Maximum Quantity Per 84 Days
Mounjaro® (tirzepatide SC injection)	2.5 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	5 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	7.5 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	10 mg/0.5 mg pen	2 mL (4 pens)	6 mL (12 pens)
	12.5 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	15 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)

SC – Subcutaneous.

Diabetes – Mounjaro Drug Quantity Management Policy – Per Days **product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

Mounjaro (all strengths)
No overrides recommended.

REFERENCES

1. Mounjaro® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New policy created to add additional quantity limits to approve ONE claim collectively for ONE glucagon-like peptide-1 (GLP-1) agonist or	07/17/2024

	GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist every 21 days at retail or home delivery. New clinical overrides apply to these limits. Existing "Per Days" quantity limits were not changed and no overrides apply.	
Early Annual Revision	The quantity limit of ONE claim of ONE glucagon-like peptide-1 (GLP-1) agonist or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist to be dispensed every 21 days at retail or home delivery was removed from this policy (refer to the "Diabetes – Glucagon-Like Peptide-1 Agonists Drug Quantity Management Policy – Claim Per Days" document for additional information).	10/30/2024