



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Diabetes – Mounjaro Drug Quantity Management Policy – Per Days

- Mounjaro® (tirzepatide subcutaneous injection – Eli Lilly)

**REVIEW DATE:** 07/17/2024

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### **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**.<sup>1</sup>

### **Dosing**

The recommended initial dose of Mounjaro is 2.5 mg administered subcutaneous (SC) once weekly (QW).<sup>1</sup> 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  $\geq 4$  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:<sup>1</sup>

- 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. Two quantity limits (Limit A and Limit B) are in place for Mounjaro and are outlined below. If the Drug Quantity Management rules are not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

**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.**

### Drug Quantity Limit A

| 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.

### CRITERIA A

Mounjaro (all strengths)

No overrides recommended.

### Drug Quantity Limit B

| Product                              | Strength and Form  | Retail and Home Delivery Maximum Quantity Per 21 Days                                                               |
|--------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------|
| Mounjaro® (tirzepatide SC injection) | 2.5 mg/0.5 mL pen  | <b>ONE claim collectively for ONE GLP-1 agonist or GLP-1/GIP agonist may be approved every 21 days.<sup>a</sup></b> |
|                                      | 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 |  |
|--|------------------|--|

SC – Subcutaneous; GLP-1 – Glucagon-like peptide-1; GIP – Glucose-dependent insulintropic peptide  
 ° Refer to Appendix A for a list of the drugs included in this limit.

## CRITERIA B

**Note:** The criteria below apply only to Quantity Limit B.

### Mounjaro (all strengths)

1. If the patient is switching from one strength of Mounjaro to another strength of Mounjaro, approve a one-time override for 2 mL (4 pens) at retail or 6 mL (12 pens) at home delivery.
2. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to Mounjaro, approve a one-time override for 2 mL (4 pens) at retail or 6 mL (12 pens) at home delivery.

**Note:** Other GLP-1 agonists and GLP-1/GIP agonists include Adlyxin® (lixisenatide SC injection), Byetta® (exenatide SC injection); Bydureon BCise® (exenatide extended-release SC injection), Ozempic® (semaglutide SC injection), Rybelsus® (semaglutide tablets), Trulicity® (dulaglutide SC injection), liraglutide SC injection (Victoza®, generic), Saxenda® (liraglutide SC injection), Wegovy® (semaglutide SC injection), Zepbound® (tirzepatide SC injection).

## 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 GLP-1/glucose-dependent insulintropic 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. | 07/17/2024  |

## APPENDIX A

**Table 1. GLP-1 Agonists and GLP-1/GIP Agonists.**

| <b>Brand (Generic Name)</b>                                  | <b>Dosage Form</b>                                                                                                                                                                                          |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Adlyxin®<br>(lixisenatide SC injection)                      | 10-20 mcg Starter Pack (discontinued)<br>20 mcg Maintenance Pack (discontinued)                                                                                                                             |
| Bydureon®<br>(exenatide extended-release SC injection)       | 2 mg/0.65 mL pen                                                                                                                                                                                            |
| Bydureon BCise®<br>(exenatide extended-release SC injection) | 2 mg/0.85 mL prefilled auto-injector                                                                                                                                                                        |
| Byetta®<br>(exenatide SC injection)                          | 5 mcg/0.02 mL dose pen (1.2 mL)<br>10 mcg/0.04 mL dose pen (2.4 mL)                                                                                                                                         |
| Mounjaro®<br>(tirzepatide SC injection)                      | 2.5 mg/0.5 mL pen<br>5 mg/0.5 mL pen<br>7.5 mg/0.5 mL pen<br>10 mg/0.5 mg pen<br>12.5 mg/0.5 mL pen<br>15 mg/0.5 mL pen                                                                                     |
| Ozempic®<br>(semaglutide SC injection)                       | 0.25 mg and 0.5 mg dose pen (2 mg/1.5 mL) [discontinued]<br>0.25 mg and 0.5 mg dose pen (2 mg/3 mL)<br>1 mg dose pen (2 mg/1.5 mL) [discontinued]<br>1 mg dose pen (4 mg/3 mL)<br>2 mg dose pen (8 mg/3 mL) |
| Rybelsus®<br>(semaglutide tablets)                           | 3 mg tablet<br>7 mg tablet<br>14 mg tablet                                                                                                                                                                  |
| Saxenda®<br>(liraglutide SC injection)                       | 18 mg/3 mL pen                                                                                                                                                                                              |
| Trulicity®<br>(dulaglutide SC injection)                     | 0.75 mg/0.5 mL pen<br>1.5 mg/0.5 mL pen<br>3 mg/0.5 mL pen<br>4.5 mg/0.5 mL pen                                                                                                                             |
| Victoza®<br>(liraglutide SC injection, generic)              | 18 mg/3 mL pen (2-pack)<br>18 mg/3 mL pen (3-pack)                                                                                                                                                          |
| Wegovy®<br>(semaglutide SC injection)                        | 0.25 mg/0.5 mL pen<br>0.5 mg/0.5 mL pen<br>1 mg/0.5 mL pen<br>1.7 mg/0.75 mL pen<br>2.4 mg/0.75 mL pen                                                                                                      |
| Zepbound®<br>(tirzepatide SC injection)                      | 2.5 mg/0.5 mL pen<br>5 mg/0.5 mL pen<br>7.5 mg/0.5 mL pen<br>10 mg/0.5 mL pen<br>12.5 mg/0.5 mL pen<br>15 mg/0.5 mL pen                                                                                     |

GLP – Glucagon-like peptide-1; GIP – Glucose-dependent insulinotropic polypeptide; SC – Subcutaneous.

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