DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Diabetes – Trulicity Drug Quantity Management Policy – Per Days
- Trulicity® (dulaglutide 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

Trulicity, a glucagon-like peptide 1 (GLP-1) agonist, is indicated:[1]
- As an adjunct to diet and exercise to improve glycemic control in adult and pediatric **patients ≥ 10 years of age with type 2 diabetes mellitus**.
- To **reduce the risk of major adverse cardiovascular events** (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Dosing

Adult Dosing

The recommended initial dose of Trulicity is 0.75 mg administered subcutaneously (SC) once weekly (QW).[1] The dose should be increased to 1.5 mg SC QW for additional glycemic control. After 4 weeks on the current dose, may increase the dose in 1.5 mg increments if additional glycemic control is needed. The maximum dose of Trulicity is 4.5 mg SC QW.

Pediatric Dosing

The recommended initial dose of Trulicity is 0.75 mg SC QW.[1] The dose may be increased to the maximum dose of 1.5 mg SC QW after at least 4 weeks on the 0.75 mg dose, if additional glycemic control is needed.

Missed Doses
If a dose of Trulicity is missed, the dose should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If there are less than 3 days prior to the next scheduled dose, the missed dose should be skipped and administered on the regularly scheduled day. In either scenario, patients may then resume their regular dosing schedule. The day of administration can be changed if needed, provided the last dose was administered 3 or more days before the new day of administration.

Availability
Trulicity is supplied as single-dose pens in cartons containing four pens each.[1] The pens are available in the following strengths:
- 0.75 mg/0.5 mL pen
- 1.5 mg/0.5 mL pen
- 3 mg/0.5 mL pen
- 4.5 mg/0.5 mL pen

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Trulicity. 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
Trulicity® (dulaglutide SC injection)	0.75 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	1.5 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	3 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)
	4.5 mg/0.5 mL pen	2 mL (4 pens)	6 mL (12 pens)

SC – Subcutaneous.

Diabetes – Trulicity 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

Trulicity (all strengths)

No overrides recommended.

REFERENCES

1. Trulicity® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.

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 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.	07/17/2024
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