DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Diabetes – Rybelsus Drug Quantity Management Policy – Per Days
- Rybelsus® (semaglutide tablets – Novo Nordisk)

REVIEW DATE: 10/30/2024; selected revision 03/12/2025

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

Rybelsus, a glucagon-like peptide 1 (GLP-1) agonist, is indicated:[1]
- As an adjunct to diet and exercise to improve glycemic control in **adults with type 2 diabetes mellitus**.

Dosing

There are two Rybelsus formulations: formulation R1 and formulation R2.[1] Each formulation has different recommended dosages. Formulation R1 includes the 3 mg, 7 mg, and 14 mg strengths, while formulation R2 includes the 1.5 mg, 4 mg, and 9 mg strengths. The formulation R1 and formulation R2 strengths cannot be substituted on a mg per mg basis. Either formulation R1 or formulation R2 may be used; do not use both formulations at the same time. Regardless of the formulation, Rybelsus should be taken on an empty stomach in the morning. Tablets should be swallowed who and cannot be split, crushed, or chewed. If a dose is missed, it should be skipped, and the patient should take the next dose the following day.

Formulation R1 Dosing

- Initiation Phase (Days 1 to 30): 3 mg once daily (QD). This dose is not effective for glycemic control.
- Escalation and Maintenance (Days 31 and beyond): 7 mg QD for 30 days. On Day 61 or after, if no additional glycemic control is needed, maintain the dose at 7 mg QD. If additional glycemic control is needed, increase the dose to 14 mg QD.

Formulation R2 Dosing
- Initiation Phase (Days 1 to 30): 1.5 mg once daily (QD). This dose is not effective for glycemic control.
- Escalation and Maintenance (Days 31 and beyond): 4 mg QD for 30 days. On Day 61 or after, if no additional glycemic control is needed, maintain the dose at 4 mg QD. If additional glycemic control is needed, increase the dose to 9 mg QD.

Switching Between Rybelsus Formulations
Do not switch between Rybelsus formulations during the initiation phase (Days 1 to 30). After 30 days, patients may switch formulations as outlined in Table 1 below. When switching, initiate the new formulation the day after discontinuing the previous formulation.

Table 1. Switching Between Escalation or Maintenance Dosage of Rybelsus Formulations.[1]

Rybelsus Formulation R1	Rybelsus Formulation R2
7 mg QD	4 mg QD
14 mg QD	9 mg QD

QD – Once daily.

Switching from Ozempic to Rybelsus
- From Ozempic to Rybelsus formulation R1: One week after discontinuing 0.5 mg of Ozempic (semaglutide subcutaneous [SC] injection), start 7 mg or 14 mg QD. Recommendations for switching from other doses of Ozempic to Rybelsus are not available.
- From Ozempic to Rybelsus formulation R2: One week after discontinuing 0.5 mg of Ozempic, start 4 mg or 9 mg QD. Recommendations for switching from other doses of Ozempic to Rybelsus are not available.

Availability
Rybelsus formulation R1 is available as 3 mg, 7 mg, and 14 mg tablets supplied in bottles of 30 tablets each.[1]

Rybelsus formulation R2 is available as 1.5 mg, 4 mg, and 9 mg tablets supplied in bottles of 30 tablets each.[1]

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

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity Per 30 Days	Home Delivery Maximum Quantity Per 90 Days
Rybelsus® (semaglutide tablets) Formulation R1	3 mg tablets	30 tablets	90 tablets
	7 mg tablets	30 tablets	90 tablets
	14 mg tablets	30 tablets	90 tablets
Rybelsus® (semaglutide tablets) Formulation R2	1.5 mg tablets	30 tablets	90 tablets
	4 mg tablets	30 tablets	90 tablets
	9 mg tablets	30 tablets	90 tablets

CRITERIA

Rybelsus (all strengths/all formulations)
No overrides recommended.

Any other exception is considered not medically necessary.

REFERENCES

1. Rybelsus® tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; December 2024.

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
Selected Revision	**Rybelsus (formulation R2) 1.5 mg, 4 mg, and 9 mg tablets:** New quantity limits of 30 tablets per 30 days at retail and 90 tablets per 90 days at home delivery were added to the policy. No clinical overrides apply.	03/12/2025