DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 07/17/2024

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

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

The recommended initial dose of Rybelsus is 3 mg once daily (QD) for 30 days.[1] The 3 mg dose is intended for treatment initiation only and is not effective for glycemic control. Following 30 days of Rybelsus 3 mg QD, increase the dose to 7 mg QD. After 30 days of 7 mg QD dosing, the dose may be increased to 14 mg QD, if additional glycemic control is needed. Taking two 7 mg tablets to achieve a 14 mg dose is not recommended. If a dose is missed, the dose should be skipped and the next dose taken on the following day. Rybelsus should be taken at least 30 minutes before the first food, beverage, or other oral medication of the day with 4 ounces of plain water. Tablets should be swallowed whole and are not to be split, crushed, or chewed.

A patient treated with Rybelsus 14 mg daily may be transitioned to Ozempic® (semaglutide subcutaneous injection) 0.5 mg once weekly (QW), starting the day

after their last dose of Rybelsus.[1] Conversely, patients treated with Ozempic 0.5 mg QW, may be transitioned to Rybelsus 7 mg or 14 mg QD. Rybelsus may be started up to 7 days following the last injection of Ozempic. There is no equivalent Rybelsus dose for the Ozempic 1 mg dose.

Availability

Rybelsus is available as 3 mg, 7 mg, and 14 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. Two quantity limits (Limit A and Limit B) are in place for Rybelsus 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 – Rybelsus 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 30 Days	Home Delivery Maximum Quantity Per 90 Days
Rybelsus® (semaglutide tablets)	3 mg tablets	30 tablets	90 tablets
	7 mg tablets	30 tablets	90 tablets
	14 mg tablets	30 tablets	90 tablets

CRITERIA A

Rybelsus (all strengths)
No overrides recommended.

Drug Quantity Limit B

Product	Strength and Form	Retail and Home Delivery Maximum Quantity Per 21 Days
Rybelsus® (semaglutide tablets)	3 mg tablets	**ONE claim collectively for ONE GLP-1 agonist or GLP-1/GIP agonist may be approved every 21 days**.[α]
	7 mg tablets	
	14 mg tablets	

GLP-1 – Glucagon-like peptide-1; GIP – Glucose-dependent insulinotropic peptide [α] 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.

Rybelsus (all strengths)

1. If the patient is switching from one strength of Rybelsus to another strength of Rybelsus, approve a one-time override for 30 tablets at retail or 90 tablets at home delivery.

2. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to Rybelsus, approve a one-time override for 30 tablets at retail or 90 tablets 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), Mounjaro® (tirzepatide SC injection), Ozempic® (semaglutide SC injection), Trulicity® (dulaglutide SC injection), liraglutide SC injection (Victoza®, generic), Saxenda® (liraglutide SC injection), Wegovy® (semaglutide SC injection), Zepbound® (tirzepatide SC injection).

REFERENCES

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

APPENDIX A

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

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

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