



DRUG QUANTITY MANAGEMENT POLICY – CLAIM PER DAYS

- POLICY:** Diabetes – Glucagon-Like Peptide-1 Agonists Drug Quantity Management Policy – Claim Per Days
- Bydureon BCise® (exenatide extended-release subcutaneous injection – AstraZeneca)
 - Byetta® (exenatide subcutaneous injection – AstraZeneca)
 - Mounjaro® (tirzepatide subcutaneous injection – Eli Lilly)
 - Ozempic® (semaglutide subcutaneous injection – Novo Nordisk)
 - Rybelsus® (semaglutide tablets – Novo Nordisk)
 - Trulicity® (dulaglutide subcutaneous injection – Eli Lilly)
 - Victoza® (liraglutide subcutaneous injection – Novo Nordisk, authorized generic)

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

The glucagon-like peptide-1 (GLP-1) receptor agonists and the GLP-1/glucose-dependent insulintropic polypeptide-1 (GIP) agonist addressed in this policy are indicated as adjuncts to diet and exercise to improve glycemic control in adults with **type 2 diabetes**.¹⁻⁷ Liraglutide, Trulicity, and Bydureon BCise are additionally indicated for type 2 diabetes in patients ≥ 10 years of age.^{2,6,7} Liraglutide, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.^{4,6,7}

The GLP-1 agonists and GLP-1/GIP agonists should not be combined with each other or with any other GLP-1 agonists or GLP-1/GIP agonists. There are other GLP-1 and GLP-1/GIP agonist products not included in this policy that are FDA-approved for chronic weight management. Refer to Appendix A for a list of GLP-1 agonists and GLP-1/GIP agonists addressed in the Claim Per Days limit.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the GLP-1 agonists and the GLP-1/GIP agonists. The Claim Per Days quantity limits outlined below can be applied alone or in conjunction with the standard Per Days limits that are in place for each individual medication. For details regarding each product's Per Days quantity limits, refer to each respective Per Days Drug Quantity Management policy. All approvals are provided for the duration noted below.

Claim Per Days Quantity Limit

Product	Strength and Form	Retail and Home Delivery Maximum Quantity
Byetta® (exenatide SC injection)	5 mcg/0.02 mL per dose prefilled pens (1.2 mL total) 10 mcg/0.04 mL per dose prefilled pens (2.4 mL total)	ONE claim collectively for ONE GLP-1 agonist or GLP- 1/GIP agonist may be approved every 21 days.^{a,β}
Bydureon BCise® (exenatide extended-release SC injection)	2 mg/0.85 mL prefilled auto- injector	
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 tablets	
	7 mg tablets	
	14 mg tablets	
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, authorized generic)	18 mg/3 mL pen (2-pack)	
	18 mg/3 mL pen (3-pack)	

SC – Subcutaneous; GLP-1 – Glucagon-like peptide-1; GIP – Glucose-dependent insulintropic peptide
^a Refer to Appendix A for a list of the drugs included in this limit; ^b This quantity limit rule only applies to claims for ≥ 28-day supply.

Diabetes – Glucagon-Like Peptide-1 Agonists Drug Quantity Management Policy – Claim 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

Byetta (all strengths)

1. If the patient is switching from one strength of Byetta to another strength of Byetta, approve a one-time override for one additional claim of Byetta at retail or home delivery.
2. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to Byetta, approve a one-time override for one additional claim of Byetta at retail or home delivery.

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

Bydureon BCise

1. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to Bydureon BCise, approve a one-time override for one additional claim of Bydureon BCise at retail or home delivery.

Note: Other GLP-1 agonists and GLP-1/GIP agonists include Adlyxin[®] (lixisenatide SC injection), Byetta[®] (exenatide SC injection), Mounjaro[®] (tirzepatide SC injection), Ozempic[®] (semaglutide SC injection), Rybelsus[®] (semaglutide tablets), Trulicity[®] (dulaglutide SC injection), liraglutide SC injection (Victoza[®], authorized generic), Saxenda[®] (liraglutide SC injection), Wegovy[®] (semaglutide SC injection), Zepbound[®] (tirzepatide SC injection).

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 one additional claim of Mounjaro at retail or 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 one additional claim of Mounjaro at retail or 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[®], authorized generic), Saxenda[®] (liraglutide SC injection), Wegovy[®] (semaglutide SC injection), Zepbound[®] (tirzepatide SC injection).

Ozempic (all strengths)

1. If the patient is switching from one strength of Ozempic to another strength of Ozempic, approve a one-time override for one additional claim of Ozempic at retail or home delivery.
2. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to Ozempic, approve a one-time override for one additional claim of Ozempic at retail or 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 subcutaneous injection), Rybelsus[®] (semaglutide tablets), Trulicity[®] (dulaglutide SC injection), liraglutide SC injection (Victoza[®], authorized generic), Saxenda[®] (liraglutide SC injection), Wegovy[®] (semaglutide SC injection), Zepbound[®] (tirzepatide SC injection).

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 one additional claim of Rybelsus at retail or 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 one additional claim of Rybelsus at retail or 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[®], authorized generic), Saxenda[®] (liraglutide SC injection), Wegovy[®] (semaglutide SC injection), Zepbound[®] (tirzepatide SC injection).

Trulicity (all strengths)

1. If the patient is switching from one strength of Trulicity to another strength of Trulicity, approve a one-time override for one additional claim of Trulicity at retail or home delivery.
2. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to Trulicity, approve a one-time override for one additional claim of Ozempic at retail or 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), Rybelsus[®] (semaglutide tablets), liraglutide SC injection (Victoza[®], authorized generic), Saxenda[®] (liraglutide SC

injection), Wegovy® (semaglutide SC injection), Zepbound® (tirzepatide SC injection).

Liraglutide subcutaneous injection (Victoza, authorized generic) 18 mg/3 mL pens (2-pack and 3-pack)

3. If the patient is switching from another GLP-1 agonist or GLP-1/GIP agonist to liraglutide subcutaneous (SC) injection (Victoza, authorized generic), approve a one-time override for one additional claim of liraglutide SC injection (Victoza, authorized generic) at retail or home delivery.

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

REFERENCES

1. Mounjaro® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.
2. Bydureon BCise® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; May 2023.
3. Byetta® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
4. Ozempic® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; September 2023.
5. Rybelsus® tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2024.
6. Trulicity® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.
7. Victoza® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/30/2024

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 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, authorized 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.

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