Pharmacy Management Drug Policy

SUBJECT: Diabetic Incretin Mimetic Agents
POLICY NUMBER: PHARMACY-112
EFFECTIVE DATE: 01/01/2024
LAST REVIEW DATE: 05/07/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Incretin mimetics are drugs used for the treatment of type 2 diabetes. These agents act like incretin hormones such as glucagon-like peptide-1 (GLP-1). They bind to GLP-1 receptors and stimulate glucose dependent insulin release, therefore act as antihyperglycemics. Incretin mimetics also suppress appetite and inhibit glucagon secretion. They slow gastric emptying and as a result prevent steep rise in post-prandial blood glucose levels.

POLICY:

Drug Name	Criteria
Exenatide Pen	Must have a diagnosis of Type 2 Diabetes Mellitus **AND** Must have experienced serious side effects or therapeutic failure of **TWO** of the following agents: Ozempic Pen/Tablet, Trulicity Pen, Mounjaro Pen, Rybelsus Tablet
Victoza Pen	
Liraglutide Pen	
Ozempic Tablet	Must have a diagnosis of Type 2 Diabetes Mellitus
Ozempic Pen	
Rybelsus Tablet	
Trulicity Pen	
Mounjaro Pen	

Drug Specific Dosing and Quantity Limits:

Drug Name	FDA approved Dose	Quantity Limit
Exenatide Pen	• Starting dosage: 5 mcg administered subcutaneously twice daily • Based on clinical response, the dose can be increased to 10 mcg twice daily after 1 month of therapy.	1 pen per 28 days
Victoza Pen	• Starting dosage: 0.6 mg injected subcutaneously once daily for one week. • After one week at the 0.6 mg once daily dosage, increase the dosage to 1.2 mg injected subcutaneously once daily • MDD: 1.8 mg once daily	3 pens (9 mL) per 30 days
Liraglutide Pen		

Ozempic Tablet	• Starting dosage: 1.5 mg once daily for 30 days • After 30 days on the 1.5 mg dosage, increase the dosage to 4 mg once daily • After 61 days, the dosage may be increased to 9 mg once daily	30 tablets per 30 days
Ozempic Pen	• Starting dosage: 0.25 mg injected subcutaneously once weekly for 4 weeks • After 4 weeks on the 0.5 mg dosage, the dosage may be increased to 1 mg once weekly • MDD: 2 mg once weekly	1 pen (3 mL) per 28 days
Rybelsus Tablet	• Starting dosage: 3 mg once daily for 30 days • After 30 days on the 3 mg-dosage, increase the dosage to 7 mg once daily • After 61 days, the dosage may be increased to 14 mg once daily	30 tablets per 30 days
Trulicity Pen	• Starting dosage: 0.75 mg injected subcutaneously once weekly. • Increase the dosage to 1.5 mg once weekly for additional glycemic control. • MDD: 4.5 mg once weekly	4 pens (2 mL) per 28 days
Mounjaro Pen	• Starting dosage: 2.5 mg injected subcutaneously once weekly • After 4 weeks, increase the dosage to 5 mg injected subcutaneously once weekly • If additional glycemic control is needed, increase the dosage in 2.5 mg increments after at least 4 weeks on the current dose • MDD: 15 mg injected subcutaneously once weekly	• 4 pens (2 mL) per 365 days of the 2.5 mg dose to allow for titration to maintenance dosing • 4 pens (2 mL) per 28 days for all other doses

Collective GLP-1 Agonist and GLP-1/GIP Agonist Quantity Limits

These limits apply cumulatively across all GLP-1 agonist and GLP-1/GIP agonist products, regardless of indication (diabetes, weight management, or weight-related comorbid condition), product, or strength.

Claim Frequency Limit

- One claim for one GLP-1 agonist or GLP-1/GIP agonist product at one strength may be approved for each 28-day or 30-day supply
    - Extended-day supplies are evaluated as multiples of standard monthly treatments (e.g., an 84day supply equals three 28-day supplies; a 90-day supply equals three 30-day supplies)
- Claims for multiple strengths of the same product or for different GLP-1 agonist or GLP-1/GIP agonist products within the same or overlapping dispensing period will not be permitted.
    - An exception may be considered when a patient is transitioning from one product to another or from one strength to another, provided that the previous product or strength is discontinued, and no further claims will be submitted for the discontinued therapy

Annual Day-Supply Limits

- Maximum of 14-28 or 30-day fills per rolling 365 days **OR** maximum of 5-84 or 90-day fills per rolling 365 days
    - When multiple day-supply durations are used, eligibility is determined based on the total number of days supplied.

- Annual day-supply limits are cumulative across all GLP-1 agonist and GLP-1/GIP agonist products and dispensing patterns.
- Switching between products, strengths, or day-supply durations does not reset or bypass cumulative annual day-supply limits.
- Eligibility for additional fills is restored only as previously dispensed day-supply amounts fall outside the rolling 365-day period.

POLICY GUIDELINES:

1. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
2. Supportive documentation of previous drug use must be submitted for any criteria requiring trial of a preferred agent if the preferred drug is not found in claims history.
3. Utilization Management is contract dependent and coverage criteria may be dependent on contract renewal date. Additionally, drug coverage is contract dependent. Refer to specific contract/benefit language for exclusions.
4. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
   a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
   c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   d. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
5. Approval will be granted for a period of 1 year.
6. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred

formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives
as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

7. In addition to the full prescribing information for each individual drug, the corresponding clinical guidelines (i.e., NCCN, DSM, etc.) are reviewed on an annual basis to determine the appropriateness of the medical necessity criteria that is applied.
8. Dose and frequency should be in accordance with the FDA label or recognized compendia (for offlabel uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
9. Please reference PHARMACY-03 Weight-Related Comorbidities Policy: Overweight, Obesity, Cardiovascular Disease for criteria applicable to the incretin mimetics, Saxenda and Wegovy.
10. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
11. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

UPDATES:

Date	Revision
05/07/2026	Revised
01/01/2026	Revised
11/13/2025	P&T Committee Review & Approval
10/28/2025	Revised
05/01/2025	Revised
03/06/2025	Revised
01/01/2025	Revised
09/13/2024	Revised
08/15/2024	P&T Committee Review & Approval
06/28/2024	Revised
06/26/2024	Revised
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08/24/2023	P&T Committee Review & Approval