Pharmacy Management Drug Policy

SUBJECT: Diabetic Incretin Mimetic Agents
POLICY NUMBER: PHARMACY-112
EFFECTIVE DATE: 1/1/2024
LAST REVIEW DATE: 03/06/2025

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
Bydureon	Coverage requires diagnosis of type 2 diabetes mellitus **AND** Failure of TWO of the following agents: Ozempic, Trulicity, Mounjaro or Rybelsus
Byetta	
Victoza	
Ozempic	Must have a Diagnosis of type 2 diabetes mellitus
Rybelsus	
Trulicity	
Liraglutide	
Mounjaro	

Drug Specific Dosing and Quantity Limits:

Drug Name	FDA approved Dose	Quantity Limit
Bydureon	• 2 mg subcutaneously once every 7 days (weekly)	4 pens per 28 days
Byetta	• Starting dosage: 5 mcg administered subcutaneously twice daily • Based on clinical response, the dose of can be increased to 10 mcg twice daily after 1 month of therapy.	1 pen per 28 days
Ozempic	• Starting dosage: 0.25 mg injected subcutaneously once weekly for 4 weeks	1 pen (3 mL) per 30 days

	• After 4 weeks on the 0.5 mg dosage, the dosage may be increased to 1 mg once weekly • MDD: 2 mg once weekly	
Rybelsus	• 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. • The dosage may be increased to 14 mg once daily	30 tablets per 30 days
Trulicity	• 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
Victoza	• 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
Mounjaro	• 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

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 off-label 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
03/06/2025	Revised
01/01/2025	Revised
09/13/2024	Revised
08/15/2024	Reviewed / P&T Committee Approval
06/28/2024	Revised
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08/24/2023	P&T Committee Review & Approval