UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3137-7
Program	Step Therapy – Diabetes Medications – GLP-1 & Dual GIP/GLP-1 Receptor Agonists
Medication	Bydureon BCise® (exenatide extended-release), Byetta® (exenatide), Mounjaro® (tirzepatide), Ozempic® (semaglutide), Rybelsus® (semaglutide), Trulicity® (dulaglutide), Victoza® (liraglutide)
P&T Approval Date	2/2020, 10/2020, 11/2021, 2/2022, 1/2023, 1/2024
Effective Date	4/1/2024

1. Background:

Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide), and Trulicity (dulaglutide), are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Bydureon BCise (exenatide extended-release), and Victoza (liraglutide) are indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus. Ozempic, Trulicity, and Victoza are also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Mounjaro (tirzepatide) is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try metformin before providing coverage for a GLP-1 receptor agonist or Mounjaro.

2. Coverage Criteria[ab]:

Authorization

A. Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity or Victoza will be approved based on the following criterion:

1. History of suboptimal response (after a three-month trial[c]), contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] In Florida, Maine, and Tennessee only, diabetes medications may be approved based on both of the following: 1) Provider attests use of this product is medically necessary; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

[c] For Connecticut, Kentucky and Mississippi business, only a 30-day trial will be required.

3. Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

- Supply limits may be in place.
- Prior Authorization/Medical Necessity may be in place
- Prior Authorization/Notification may be in place

4. References:

1. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
2. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2023.
3. Mounjaro [package insert] Indianapolis, IN: Eli Lilly and Company; July 2023.
4. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; September 2023.
5. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2022.
6. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2022.
7. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2023.
8. American Diabetes Association. Standard of Medical Care in Diabetes - 2023. Diabetes Care 2023;46 (Supplement 1).

Program	Step Therapy – Diabetes Medication – GLP-1 & Dual GIP/GLP-1 Receptor Agonists
Change Control	
Date	Change
2/2020	New program.
10/2020	Removed the lookback for metformin, the sample pack language, and updated references.
2/2021	Administrative change. Update Oxford effective date.
11/2021	Annual review. Updated references.
2/2022	Added Florida, Maine, and Tennessee mandate language. Updated references.
1/2023	Annual review. Added Mounjaro to criteria. Added metformin lookback. Removed Bydureon. Updated mandate language and references.
1/2024	Annual review. Removed Adlyxin. Updated state mandate language. Updated references.