UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2246-5
Program	Prior Authorization/Medical Necessity – Custom Oxford SoNY and SoCT – GIP/GLP-1 Receptor Agonists
Medication	Adlyxin (lixisenatide), Bydureon (exenatide extended-release), 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, 7/2021, 11/2021, 9/2022
Effective Date	Oxford: 12/1/2022

1. Background:

Adlyxin (lixisenatide), 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 (exenatide extended-release), 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.

2. Coverage Criteria[a]:

A. Authorization

1. Adlyxin, Bydureon, Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, **Trulicity or Victoza** will be approved based on **all** of the following criteria:

    1. Diagnosis of type 2 diabetes mellitus confirmed by accepted laboratory testing methodologies per treatment guidelines (e.g., A1C greater than or equal to 6.5%, fasting plasma glucose (FPG) greater than or equal to 126 mg/dL and/or 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL)

    -AND-

    2. Use is not intended solely for the purpose of weight loss*

    -AND-

3. History of suboptimal response (after a three-month trial[b]), 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] For Connecticut business, only a 60-day trial will be required.

*Medications used for the purposes of weight loss are typically excluded from benefit coverage. Coverage is determined by the member's prescription drug benefit plan.

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.

4. References:

1. Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2022.
2. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2022.
3. Bydureon [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2022.
4. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2022.
5. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2022.
6. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022.
7. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2022.
8. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022.
9. American Diabetes Association. Standard of Medical Care in Diabetes - 2022. Diabetes Care 2022;45 (Supplement 1).
10. Mounjaro [package insert] Indianapolis, IN: Eli Lilly and Company; May 2022.

Program	Prior Authorization/Medical Necessity – Diabetes Medication – GLP-1 Receptor Agonists
Change Control	
Date	Change
2/2020	New program.
10/2020	Added requirement for diabetes indication. Removed grandfathering.

7/2021	Program type changed from Prior Authorization/Notification (P 1309-2) to Prior Authorization/Medical Necessity (P 2246-3)
11/2021	Annual review. Updated references and background.
9/2022	Added Mounjaro to program. Updated criteria to confirm diagnosis of diabetes with laboratory testing and use is not solely for weight loss. Removed reauthorization. Added three-month trial requirement and CT footnote. Updated references.