UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 2246-7 |
| Program | Prior Authorization/Medical Necessity – Custom Oxford SoNY and SoCT – 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, 7/2021, 11/2021, 9/2022, 1/2023, 5/2023 |
| Effective Date | Oxford: 8/1/2023 |

## 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.

Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity and Victoza are only indicated for the treatment of type 2 DM and are not FDA approved for the treatment of weight loss.

## 2. Coverage Criteria[a,b]:

**A. Authorization**

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

   a. Submission of medical records (e.g., chart notes) confirming **one** of the following:

      (1) Diagnosis of type 2 diabetes mellitus as evidenced by **one** of the following laboratory values:

         i. A1C greater than or equal to 6.5%
         ii. Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL

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iii. 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test

**-OR-**

(2) For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e. diagnosed greater than 2 years ago), submission of medical records (e.g. chart notes) confirming diagnosis of type 2 diabetes mellitus

**-AND-**

b. 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] Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza are not FDA approved for the treatment of weight loss. 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**.**
[c] For Connecticut business, only a 60-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.

**4. References:**


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


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9. Consensus Statement by The American Association Of Clinical Endocrinologists and American College Of Endocrinology On The Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary. AACE/ACE Consensus Statement. *Endocr Pract.* 2020;26: 107-39.

| Program | Prior Authorization/Medical Necessity – Custom Oxford SoNY and SoCT – GLP-1 & Dual GIP/GLP-1 Receptor Agonists |
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| **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. |
| 1/2023 | Removed Bydureon. Updated program name with Dual GIP/GLP-1. |
| 5/2023 | Removed Adlyxin. Added medical records requirement for diagnosis of type 2 diabetes. Separated criteria for existing and new diagnosis for diabetes. |

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