



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

|                   |   |
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| Program Number    | 2020 P 3137-3   |
| Program           | Step Therapy – Diabetes Medications – GLP-1 Receptor Agonists   |
| Medication        | Adlyxin (lixisenatide), Bydureon (exenatide extended-release), Bydureon BCise (exenatide extended-release), Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), Victoza (liraglutide) |
| P&T Approval Date | 2/2020, 10/2020   |
| Effective Date    | 1/1/2021;<br>Oxford only: 1/1/2021  |

**1. Background:**

Adlyxin (lixisenatide), Bydureon (exenatide extended-release), Bydureon BCise (exenatide extended-release), Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), and Victoza (liraglutide) are indicated as an adjunct to diet and exercise to improve glycemic control in adults 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.

**2. Coverage Criteria<sup>a</sup>:**

**Authorization**

**A. Adlyxin, Bydureon, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity and Victoza will be approved based on the following criterion:**

1. History of suboptimal response, contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

**Authorization will be issued for 12 months.**

<sup>a</sup> 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.

**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. Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; January 2019.
2. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2020.
3. Bydureon [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2020.
4. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2020.
5. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2020.
6. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2020..
7. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2020.
8. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; August 2020.
9. American Diabetes Association. Standard of Medical Care in Diabetes - 2020. Diabetes Care 2020;43 (Supplement 1)..

| Program               | Step Therapy – Diabetes Medication – GLP-1 Receptor Agonists                          |
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| <b>Change Control</b> |   |
| 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.                                  |