



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; 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^a:

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.

^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.

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)..

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| 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. |