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 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.

   If a member has a prescription for metformin in claims history within the previous 12 months, the claim for Adlyxin, Bydureon, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity or Victoza will automatically process. Members currently on Adlyxin, Bydureon, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity or Victoza as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. **Coverage Criteria**

   **Authorization**

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

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

      -OR-

   2. **Both** of the following:

      a. Currently on therapy with Adlyxin, Bydureon, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity or Victoza and is requesting continuation of the same therapy.
b. **One** of the following:

   (1) Patient has **not** received a manufacturer supplied sample at no cost as a means to establish as a current user of Adlyxin, Bydureon, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity or Victoza.

   -OR-

   (2) **Both** of the following:

   i. Patient has received a manufacturer supplied sample at no cost as a means to establish as a current user of Adlyxin, Byetta, Bydureon, Bydureon BCise, Ozempic, Rybelsus, Trulicity and Victoza

   -AND-

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

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

* 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.

4. **References:**


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9. American Diabetes Association; Pharmacologic Approaches to Glycemic Treatment: Executive Summary: Standards of Medical Care in Diabetes 2012-2018, Diabetes Care 2018 Jan; 41 (Supplement 1):S73-S85.4-S10.
10. American Diabetes Association; Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes. Diabetes Care 2018 Jan; 41(Supplement 1): S86-S104.

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<th>Step Therapy – Diabetes Medication – GLP-1 Receptor Agonists</th>
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