UnitedHealthcare®

Clinical Pharmacy Program Guidelines for GLP-1 Agonists

Program	Prior Authorization
Medication	**Preferred Products:** Adlyxin (lixisenatide), Victoza 2 Pen Pack (liraglutide injection), Trulicity (dulaglutide) **Non-Preferred Products:** Victoza (liraglutide) 3 Pen Pack, Bydureon (exenatide extended-release), Bydureon BCise (exenatide extended-release), Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide)
Markets in Scope	Hawaii, California, Maryland, New York, Nevada, New Jersey, Pennsylvania- CHIP, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Adlyxin, Byetta, Bydureon, Bydureon BCise, and Rybelsus are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Bydureon and Bydureon BCise are extended-release formulations of exenatide.

Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Ozempic is also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Trulicity is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Trulicity is also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Victoza is indicated as an adjunct to diet and exercise to improve glycemic control in adults and children 10 years and older with type 2 diabetes mellitus. Victoza is also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

2. Coverage Criteria:

A. Victoza 1.2mg per day (2 Pen Pack), Adlyxin or Trulicity

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

Authorization will be issued for 12 months.

B. Victoza 1.8mg per day (3 Pen Pack)

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

-AND-

3. History of failure to achieve acceptable glycemic control with Victoza 1.2mg per day for 90 days (2 Pen Pack)

-AND-

4. History of failure to Trulicity for 90 days, or contraindication or intolerance to Trulicity

Authorization will be issued for 12 months.

C. Bydureon, Bydureon BCise, Byetta, or Ozempic

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

-AND-

3. History of failure for 90 days or intolerance or contraindication to **two** of the following:
    - Adlyxin
    - Victoza 1.2mg per day (2 Pen Pack)
    - Trulicity

Authorization will be issued for 12 months.

D. Rybelsus

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

-AND-

3. **One** of the following:
    a. History of failure for 90 days or intolerance or contraindication to **two** of the following:
        - Adlyxin
        - Victoza 1.2mg per day (2 Pen Pack)
        - Trulicity

    -OR-

    b. **Both** of the following:
        i. The patient is unable to self-inject due to **one** of the following:
            - Physical impairment
            - Visual impairment
            - Lipohypertrophy
            - Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

        -AND-

        ii. History of failure, intolerance, or contraindication to **one** of the following:

- Steglatro
- Segluromet

Authorization will be issued for 12 months.

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, Inc.; February 2020.
2. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2019.
3. Bydureon [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals, Inc.; February 2020.
4. Trulicity [package insert]. Indianapolis, IN: Eli Lily and Company; February 2020.
5. Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis US, LLC.; January 2019.
6. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk; January 2020.
7. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals, Inc.; February 2020.
8. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2020.
9. American Diabetes Association. Standards of Medical Care in Diabetes- 2019. *Diabetes Care* 2020;43 (Supplement 1)
10. Davies MJ, et al; Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetologia 2018.

Program	Prior Authorization –GLP-1 Agonists
Change Control	
Date	Change
Sept 2009	Criteria were taken from a previously approved Unison policy, RX06 Byetta. Changed prerequisite to metformin + a sulfonylurea or a TZD instead of requiring both a sulfonylurea and a TZD.

	Policy was reformatted.
June 2010	Victoza was added to the criteria
March 2011	Annual Review
December 2011	Added insulin glargine (Lantus) to section III.A.1.(2)(c) as an acceptable previous alternative medication trial. Changed insulin requirement in section III.A.1.(3)(c) requiring that the patient is not concurrently taking insulin other than insulin glargine (Lantus). Created new section for Victoza initial therapy in section III.B as Victoza and Byetta no longer have the same requirements due to new Byetta indication.
June 2012	Removed section III.B, due to Victoza and Byetta both gaining the indication to be used in combination with basal insulin. This section was used to specify Victoza not being approved for use in combination with basal insulin. Added DPP-4 drug class as an option III.A.1.(2). Updated section III.A.1.(3) to specify “not being used in combination with prandial insulin.”
December 2014	Updated criteria to align with current UHC clinical criteria template. Non-Preferred criteria section created for review of non-preferred GLP-1 products (Bydureon, Byetta, and Trulicity). Requires type 2 diabetes diagnosis, and trial of metformin at a minimum of 1500 mg per day for 90 days, and a history of failure, intolerance, or contraindication to the preferred GLP-1 products (Victoza and Tanzeum). Byetta moved to non-preferred drug criteria section due to removal from PDL. Tanzeum added to preferred drug criteria section due to addition to the PDL. Step therapy criteria rewritten for preferred products (Victoza 1.2 mg/day and Tanzeum) to require type 2 diabetes diagnosis and trial of metformin at a minimum of 1500 mg per day for 90 days. New step therapy criteria added for Victoza 1.8 mg per day, requires failure to achieve acceptable glycemic control with 1.2 mg dose.

October 2016	Added authorization durations and updated policy template
2/2017	Added Adlyxin to policy
4/2017	Updated preferred/non-preferred product list in the header. Updated non-preferred product criteria.
10/2017	Changed step therapy language to step through two preferred products rather than stepping through all since Tanzeum is being removed from the market.
12/2017	Added step through metformin in the non-preferred section to align with the preferred section.
4/2018	Added Bydureon BCise and Ozempic to policy. Updated background and references. Tanzeum removed from policy due to manufacturer discontinuation in July 2018.
6/2019	Updated program to reflect changes in 2018 ADA guidelines. Victoza 2 Pen Pack added to preferred products. Trulicity is now non-preferred product.
9/2019	Updated language to clarify failure of metformin.
10/2019	Updated policy to reflect that Trulicity will not be removed as a preferred product for 10/1/19.
11/2019	Added criteria for Rybelsus.
6/2020	Updated background to reflect additional indications for Trulicity and Ozempic.