UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for GLP-1 Agonists

Program	Prior Authorization
Medication	**Preferred Products:** Tanzeum (albiglutide), Trulicity (dulaglutide), Adlyxin (lixisenatide) **Non-Preferred Products:** Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	12/2017
Effective Date	2/2018

1. Background:

Adlyxin, Byetta, Tanzeum, Trulicity, and Victoza are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Bydureon is a 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 in multiple clinical settings. It is an extended-release formulation of exenatide. Do not co-administer with Byetta (exenatide).

2. Coverage Criteria:

A. <u>Adlyxin, Tanzeum, Trulicity</u>

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

-AND-

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

Authorization will be issued for 12 months.

B. <u>Bydureon, Byetta, or Victoza</u>

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

-AND-

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

-AND-

3. History of failure, intolerance, or contraindication to two of the following:

- Adlyxin
- Tanzeum
- Trulicity

Authorization will be issued for 12 months.

3. References:

1. Byetta Prescribing Information. Amylin Pharmaceuticals, Inc., February 2013.
2. Victoza Prescribing Information. Novo Nordisk Inc., April 2013.
3. Bydureon Prescribing Information. Amylin Pharmaceuticals, May 2014.
4. Inzucchi SE, et al; Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetologia 2012;55:1577-96
5. AACE Comprehensive Diabetes Management Algorithm, Endocr Pract. 2013;19 (No. 2)
6. American Diabetes Association. Approaches to glycemic treatment. Sec. 7. Diabetes Care. 2015;38(Suppl. 1):S41–S48.
7. Tanzeum Prescribing Information. GlaxoSmithKline, April 2014.
8. Trulicity Prescribing Information. Eli Lily and Company, September 2014.
9. Adlyxin Prescribing Information. Sanofi, July 2016.

Program	Prior Authorization –GLP-1 Agonists
Change Control	
Date	Change
9/2009	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.
6/2010	Victoza was added to the criteria

3/2011	Annual Review
12/2011	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.
6/2012	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.”
12/2014	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.
10/2016	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.