VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Diabetes – Glucagon-Like Peptide-1 Agonists Prior Authorization Policy

- Adlyxin® (lixisenatide subcutaneous injection – sanofi-aventis)
- Bydureon® (exenatide extended-release subcutaneous injection – AstraZeneca [obsolete 03/10/2021])
- Bydureon BCise® (exenatide extended-release subcutaneous injection – AstraZeneca)
- Byetta® (exenatide subcutaneous injection – AstraZeneca)
- Ozempic® (semaglutide subcutaneous injection – Novo Nordisk)
- Rybelsus® (semaglutide tablets – Novo Nordisk)
- Trulicity® (dulaglutide subcutaneous injection – Eli Lilly)
- Victoza® (liraglutide subcutaneous injection – Novo Nordisk)

REVIEW DATE: 11/16/2022; selected revision 11/30/2022 and 03/01/2023

OVERVIEW

The glucagon-like peptide-1 (GLP-1) receptor agonists addressed in this policy are indicated as adjuncts to diet and exercise to improve glycemic control in adults with **type 2 diabetes**.[1-8] Victoza, Trulicity, and Bydureon/Bydureon BCise are additionally indicated for type 2 diabetes in patients ≥ 10 years of age.[2,3,7,8] Victoza, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.[5,7,8]

Guidelines

According to the American Diabetes Association Standards of Care (2022), first-line therapy for type 2 diabetes depends on comorbidities, patient-centered treatment factors, and management needs and generally includes metformin and comprehensive lifestyle modification.[9] Among patients with type 2 diabetes with established atherosclerotic CV disease (ASCVD) or indicators of high ASCVD risk, GLP-1 agonists with proven CV benefit (i.e., label indication of reducing CV disease events) are preferred as add-on therapy; sodium glucose co-transporter-2 (SGLT-2) inhibitors are an alternative. Other medications (GLP-1 agonists, SGLT-2 inhibitors), with or without metformin based on glycemic needs, are appropriate initial therapy for patients with type 2 diabetes with ASCVD or high ASCVD risk and/or chronic kidney disease.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of the GLP-1 agonists targeted in this policy. Of note, Saxenda® (liraglutide subcutaneous injection) and Wegovy® (semaglutide subcutaneous injection) are indicated for chronic weight management, not diabetes, and are not targeted in this policy. All approvals are provided for the duration noted below.

Automation: The following automation is applied in this policy:

- **Adlyxin, Byetta, Ozempic, Rybelsus:** If criteria for previous use of an oral medication for diabetes (not including Rybelsus or single-entity metformin) in the past 130 days are not met at the point of service, OR if the patient is < 18 years of age, coverage will be determined by Prior Authorization criteria.
- **Bydureon, Bydureon BCise, Trulicity, Victoza:** If criteria for previous use of an oral medication for diabetes (not including Rybelsus or single-entity metformin) in the past 130 days are not met at the point of service, OR if the patient is < 10 years of age, coverage will be determined by Prior Authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Type 2 Diabetes Mellitus.** Approve for 1 year if the patient meets one of the following (A or B):
   A) Adlyxin, Byetta, Ozempic, Rybelsus: Approve if the patient is ≥ 18 years of age.
   B) Bydureon, Bydureon BCise, Trulicity, Victoza: Approve if the patient is ≥ 10 years of age.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage is not recommended in the following situations:

1. **Type 1 Diabetes Mellitus.** None of the GLP-1 agonists are indicated for patients with type 1 diabetes.[1-8] Addition of GLP-1 receptor agonists to insulin therapy resulted in small (0.2%) reductions in HbA_{1C} among patients with type 1 diabetes compared with insulin alone.[9]

2. **Weight Loss Treatment**. Saxenda contains the same chemical entity as Victoza and is indicated at a higher dose for chronic weight management. Wegovy contains the same chemical entity as Ozempic and is indicated at a higher dose for chronic weight management. Endocrine Society guidelines for pharmacological management of obesity (2015) advise against off-label prescribing of medications such as GLP-1 receptor agonists for the sole purpose of producing weight loss.[10]

3. **Prediabetes/Diabetes Prevention.** GLP-1 agonists are not indicated in this setting.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Adlyxin® subcutaneous injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; June 2022.
2. Bydureon® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
3. Bydureon BCise® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
4. Byetta® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
5. Ozempic® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2022.
6. Rybelsus® tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2022.
7. Trulicity® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.
8. Victoza® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2020.
9. American Diabetes Association. Standards of medical care in diabetes – 2022. *Diabetes Care*. 2022;45(Suppl 1):S1-S258.
10. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(2):342-362.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. Tanzeum was removed from the list of targeted medications; this product is obsolete.	11/17/2021
Selected Revision	**Automation:** Automation was removed from the policy. Previously, automation was in place such that if a patient had a claim for one oral medication for diabetes within the 130-day look-back period, the claim would adjudicate. **Type 2 Diabetes Mellitus:** The approval duration was changed from 3 years to 1 year. Additionally, a requirement was added for Adlyxin, Byetta, Ozempic, Rybelsus, and Trulicity that the patient is ≥ 18 years of age. A requirement was added for Bydureon, Bydureon BCise, and Victoza that the patient is ≥ 10 years of age.	06/22/2022
Selected Revision	**Automation:** The policy was revised to reflect that automation is in place such that if a patient has a claim for one oral medication for diabetes within a 130-day lookback period, the claim will adjudicate. **Type 2 Diabetes Mellitus:** The requirement regarding age ≥ 10 years (Victoza, Bydureon, and Bydureon BCise) and age ≥ 18 years (all others) was removed from the policy.	08/31/2022
Selected Revision	**Automation:** The automation was updated to include an age requirement as follows: For Adlyxin, Byetta, Ozempic, Rybelsus, and Trulicity, if the patient has a claim for one oral medication for diabetes within a 130-day lookback AND the patient is ≥ 18 years of age, the claim will adjudicate. For Bydureon, Bydureon BCise, and Victoza, if the patient has a claim for one oral medication for diabetes within a 130-day lookback AND the patient is ≥ 10 years of age, the claim will adjudicate. It was also clarified that Rybelsus (semaglutide tablets), an oral glucagon-like peptide-1 agonist, does not satisfy the requirement for a trial of an oral medication for diabetes. **Type 2 Diabetes Mellitus:** A requirement was added for Adlyxin, Byetta, Ozempic, Rybelsus, and Trulicity that the patient is ≥ 18 years of age. A requirement was added for Bydureon, Bydureon BCise, and Victoza that the patient is ≥ 10 years of age. **Conditions Not Recommended for Approval:** The condition of "Prediabetes/Diabetes Prevention" was added to Conditions Not Recommended for Approval.	09/21/2022
Annual Revision	No criteria changes.	11/16/2022
Selected Revision	**Trulicity:** Automation and criteria were updated to reflect that the age of approval for Trulicity has been lowered from 18 years of age to 10 years of age. In automation, a claim for Trulicity will adjudicate if the patient meets the lookback for one oral medication for diabetes and the patient is ≥ 10 years of age (previously ≥ 18 years of age). In criteria, Trulicity will approve for a diagnosis of type 2 diabetes if the patient is ≥ 10 years of age (previously ≥ 18 years of age).	11/30/2022
Selected Revision	**Automation:** Automation for all products was updated to remove single-entity metformin as an oral medication that has been used for diabetes in the past 130 days. Previously, Rybelsus was the only oral agent not included in this automation.	03/01/2023