



## 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**.<sup>1-8</sup> Victoza, Trulicity, and Bydureon/Bydureon BCise are additionally indicated for type 2 diabetes in patients  $\geq 10$  years of age.<sup>2,3,7,8</sup> Victoza, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.<sup>5,7,8</sup>

### 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.<sup>9</sup> 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

Preauthorization is required for prescription benefit coverage of the GLP-1 agonists for Type 2 Diabetes targeted in this policy. All preauthorization requests must include the member's diagnosis. 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.

**Step therapy:** The following step therapy 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 Required for approval

- 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  $\geq 18$  years of age.
  - B) Bydureon, Bydureon BCise, Trulicity, Victoza:** Approve if the patient is  $\geq 10$  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.<sup>1-8</sup> Addition of GLP-1 receptor agonists to insulin therapy resulted in small (0.2%) reductions in HbA<sub>1C</sub> among patients with type 1 diabetes compared with insulin alone.<sup>9</sup>
- 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.<sup>10</sup>
- 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<sup>®</sup> subcutaneous injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; June 2022.
2. Bydureon<sup>®</sup> subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
3. Bydureon BCise<sup>®</sup> subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
4. Byetta<sup>®</sup> subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
5. Ozempic<sup>®</sup> subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2022.
6. Rybelsus<sup>®</sup> tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2022.
7. Trulicity<sup>®</sup> subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.
8. Victoza<sup>®</sup> 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.