

## 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

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### 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

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) 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) 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  $\geq 18$  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>1-7</sup>  
<sup>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.

