PRIOR AUTHORIZATION POLICY

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

- Adlyxin® (lixisenatide injection – sanofi-aventis)
- Bydureon® (exenatide extended-release injectable suspension – AstraZeneca)
- Bydureon BCise® (exenatide extended-release injectable suspension – AstraZeneca)
- Byetta® (exenatide injection – AstraZeneca)
- Ozempic® (semaglutide injection – Novo Nordisk)
- Rybelsus® (semaglutide tablets – Novo Nordisk)
- Tanzeum™ (albiglutide injection – GlaxoSmithKline [obsolete 07/31/2018])
- Trulicity® (dulaglutide injection – Eli Lilly)
- Victoza® (liraglutide injection – Novo Nordisk)

REVIEW DATE: 10/21/2020

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.[1-9] Victoza is additionally indicated for type 2 diabetes in patients ≥ 10 years of age.[9] Victoza, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.

Guidelines

According to the ADA Standards of Care (2020), among patients with type 2 diabetes with established atherosclerotic CV disease, sodium-glucose co-transporter 2 inhibitors or GLP-1 agonists with demonstrated CV disease benefit are recommended as part of the antihyperglycemic regimen.[10] GLP-1 agonists are also useful as add-on therapy for patients who are inadequately controlled on metformin. Other guidelines have similar recommendations.[11]

POLICY STATEMENT

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

Automation: If criteria for previous use of an oral medication for diabetes (this includes all oral medications for diabetes) in the past 130 days are not met at the point of service, coverage will be determined by prior authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Type 2 Diabetes Mellitus.** Approve for 3 years.

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.[1-9] 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.[10]

2. **Weight Loss Treatment**. Saxenda contains the same chemical entity as Victoza at a higher dosage and is indicated 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.[12]

3. 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® injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; January 2019.
2. Bydureon® injectable suspension [prescribing information]. Wilmington, DE: AstraZeneca; February 2020.
3. Bydureon BCise® injectable suspension [prescribing information]. Wilmington, DE: AstraZeneca; February 2020.
4. Byetta® injection [prescribing information]. Wilmington, DE: AstraZeneca; February 2020.
5. Ozempic® injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2020.
6. Rybelsus® tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2020.
7. Tanzeum™ injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
8. Trulicity® injection [prescribing information]. Indianapolis, IN: Eli Lilly; September 2020.
9. Victoza® injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; August 2020.
10. American Diabetes Association. Standards of medical care in diabetes – 2020. *Diabetes Care*. 2020;43(Suppl 1):S1-S212. Available at: https://care.diabetesjournals.org/content/43/Supplement_1. Accessed on October 15, 2020.
11. Garber AJ, Handelsman Y, Grunberger G, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2020 executive summary. *Endocr Pract*. 2020;26(1):107-139.
12. 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. Available at: https://academic.oup.com/jcem/article/100/2/342/2813109. Accessed on October 15, 2020.