MEDICAL MUTUAL®

Drug Policy

Policy:	**Glucagon-Like Peptide-1 (GLP-1) Agonists**	**Annual Review Date:** **02/17/2022**
Impacted Drugs:	• **Victoza (liraglutide)** • **Adlyxin (lixisenatide)**	**Last Revised Date:** **02/17/2022**

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**. Victoza and Bydureon/Bydureon BCise are additionally indicated for type 2 diabetes in patients ≥ 10 years of age. Victoza, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 12 months in duration.

Basic and National Preferred Formularies:

Preferred Medications

- Bydureon (exenatide extended-release)
- Bydureon BCise
- Byetta (exenatide)
- Ozempic (semaglutide inection)
- Rybelsus (semaglutide oral tablet)
- Trulicity (dulaglutide)

Non-Preferred Medication

- Victoza (liraglutide [rDNA origin])
- Adlyxin (lixisenatide)

PREFERRED STEP THERAPY CRITERIA (FOR APPLICABLE REVIEWS)

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given

2. No other exceptions are recommended.

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Approval Duration: 365 days (1 year)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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REFERENCES

1. Bydureon® injectable suspension [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2018.
2. Byetta® injection [prescribing information]. Princeton, NJ: Bristol Myers Squibb Company; June 2021.
3. Victoza® injection [prescribing information]. Bagsvaerd, Denmark: NovoNordisk; November 2020.
4. Trulicity™ for subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; September 2021.
5. Garber AJ, Abrahamson MJ, Barzilay JI, 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. Available at: https://www.endocrinepractice.org/article/S1530-891X(20)35066-7/fulltext. Accessed on December 9, 2021.
6. Zaccardi F, Htike Z, Webb DR, et al. Benefits and harms of once-weekly glucagon-like peptide-1 receptor agonist treatments. *Ann Intern Med.* 2016;164(2):102-113.
7. Marso SP, Poulter NR, Nissen SE, et al. Design of the liraglutide effect and action in diabetes: evaluation of cardiovascular outcomes results (LEADER) trial. *AMHeart J.* 2013;166(5):823-830.
8. Marso SP, Daniels GH, Frandsen KB, et al; for the LEADER Steering Committee on behalf of the LEADER Trial Investigators. Liraglutide and cardiovascular outcomes in type 2 diabetes. *N Engl J Med*. 2016;375:311-322.
9. Bydureon® BCise™ for injectable suspension [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
10. American Diabetes Association. Standards of medical care in diabetes – 2021. *Diabetes Care.* 2021;41(suppl 1):S1-S232. Available at: https://care.diabetesjournals.org/content/diacare/suppl/2020/12/09/44.Supplement_1.DC1/DC_44_S1_final_copyright_stamped.pdf Accessed on December 9, 2021.
11. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology – clinical practice guidelines for developing a diabetes mellitus comprehensive care plan – 2015. https://www.aace.com/files/dm-guidelines-ccp.pdf. Accessed on October 5, 2018.
12. Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycemia in type 2 diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care.* 2018 [epub ahead of print]. Available at: http://care.diabetesjournals.org/content/early/2018/09/27/dci18-0033. Accessed on October 9, 2018.
13. Ozempic® [prescribing information]. Plainsboro, NJ: Novo Nordisk; April 2021.
14. Adlyxin™ injection [prescribing information]. Bridgewater, NJ: Sanofi-aventis US; July 2021.
15. Rybelsus [prescribing information]. Bagsvaerd, Denmark: Novo Nordisk; April 2021.