JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS142
		Effective Date	10/20/2021
		Review Date	05/02/2023
	Subject **Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists: Ozempic, Rybelsus, Trulicity, Victoza, Adlyxin, Bydureon BCise, Byetta, Mounjaro**	*Revision Date*	05/02/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Adlyxin, Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza

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I. POLICY

A. Adlyxin (lixisenatide), Bydureon BCise (exenatide), Byetta (exenatide), Ozempic (semaglutide), Rybelsus (oral semaglutide), Trulicity (dulaglutide), Victoza (liraglutide), and Mounjaro (tirzepatide) will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Rybelsus** may be approved for patients who meet the following:
   1. Glycemic Control in Diabetes Mellitus
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:
         I. Diagnosis of diabetes mellitus type 2
         II. Patient has had an inadequate response to at least a 3-month trial of an optimally dosed regimen of metformin, unless the use of metformin is contraindicated

B. **Ozempic** may be approved for patients who meet the following:
   1. Glycemic Control in Diabetes Mellitus
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:

I. Diagnosis of diabetes mellitus type 2
II. Patient has had an inadequate response to at least a 3-month trial of an optimally dosed regimen of metformin, unless the use of metformin is contraindicated

2. Major Cardiovascular Event Risk Reduction in Diabetes Mellitus and established Cardiovascular Disease
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes and either a history of, or risk factors for at least one of the following:
      I. coronary artery disease
      II. stroke
      III. peripheral artery disease
      IV. chronic kidney disease
      V. heart failure

C. **Trulicity** or **Victoza** may be approved for patients who meet the following:
   1. Glycemic Control in Diabetes Mellitus
      a. Patient is 10 years of age or older
      b. Documentation has been submitted showing the following:
         I. Diagnosis of diabetes mellitus type 2
         II. Patient has had an inadequate response to at least a 3-month trial of an optimally dosed regimen of metformin, unless the use of metformin is contraindicated
   2. Major Cardiovascular Event Risk Reduction in Diabetes Mellitus and established Cardiovascular Disease
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes and either a history of, or risk factors for at least one of the following:
         I. coronary artery disease
         II. stroke
         III. peripheral artery disease
         IV. chronic kidney disease
         V. heart failure

D. **Mounjaro** may be approved for patients who meet the following:
   1. Glycemic Control in Diabetes Mellitus
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:
         I. Diagnosis of diabetes mellitus type 2
         II. Patient has had an inadequate response to at least a 3-month trial of an optimally dosed regimen of metformin, unless the use of metformin is contraindicated
         III. Patient has had a trial and inadequate response to at least one of the following formulary alternatives: Ozempic, Rybelsus, Trulicity, or Victoza, unless the patient has a contraindication to the use of these agents

E. **Adlyxin** or **Byetta** may be approved for patients who meet the following:
   1. Glycemic Control in Diabetes Mellitus
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:
         I. Diagnosis of diabetes mellitus type 2

II. Patient has had an inadequate response to at least a 3-month trial of an optimally dosed regimen of metformin, unless the use of metformin is contraindicated
III. Patient has had a trial and inadequate response to at least two of the following formulary alternatives: Ozempic, Rybelsus, Trulicity, or Victoza, unless the patient has a contraindication to the use of these agents

F. **Bydureon BCise** may be approved for patients who meet the following:
1. Glycemic Control in Diabetes Mellitus
a. Patient is 10 years of age or older
b. Documentation has been submitted showing the following:
I. Diagnosis of diabetes mellitus type 2
II. Patient has had an inadequate response to at least a 3-month trial of an optimally dosed regimen of metformin, unless the use of metformin is contraindicated
III. Patient has had a trial and inadequate response to at least two of the following formulary alternatives: Ozempic, Rybelsus, Trulicity, or Victoza, unless the patient has a contraindication to the use of these agents
i. *Caveat for pediatric patients between 10 and 17 years of age:
1. Documentation of trial and inadequate response, or contraindication to both metformin and Victoza is required.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approval will be for the term of the member's enrollment.

IV. EXCLUSIONS

A. The GLP-1 agonists will not be approved for the following:
1. Treatment of type 1 diabetes mellitus
2. Weight management (agents used for weight control are excluded from the benefit per COMAR)
3. Concurrent use with another GLP-1 agonist
4. Any indications that are not FDA-approved, or guideline-supported
5. Additional drug-specific exclusions:
a. Adlyxin and Byetta will also not be approved for use in pediatric patients
b. Ozempic and Rybelsus will also not be approved for the following:
I. Use in pediatric patients
II. Patients with a personal or family history of medullary thyroid carcinoma (MTC)
III. Patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
c. Bydureon BCise, Trulicity, and Victoza will also not be approved for the following:
I. Use in pediatric patients that are younger than 10 years of age
II. Patients with a personal or family history of medullary thyroid carcinoma (MTC)
III. Patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Victoza [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; June 2022.
2. Ozempic [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; March 2022.

3. Rybelsus [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; April 2021.
4. Byetta [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2021.
5. Adlyxin [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; July 2021.
6. Bydureon BCise [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
7. Trulicity [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2022.
8. Mounjaro [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2022.
9. American Diabetes Association. 6. Glycemic Targets: Standards of Care in Diabetes - 2023. Diabetes Care 2023;46(Suppl. 1):S97–S110.
10. American Diabetes Association. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes - 2023. Diabetes Care 2023;46(Suppl. 1):S140–S157.
11. American Diabetes Association. 14. Children and Adolescents: Standards of Care in Diabetes - 2023 Diabetes Care 2023;46(Suppl. 1):S230–S253.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/20/2021	Policy Creation
07/20/2022	Update clinical criteria for new cardiovascular prevention indications
01/18/2023	Added Mounjaro as an applicable drug
04/19/2023	Revised clinical criteria
05/02/2023	Revised clinical criteria

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