# GLP-1 Agonists and Combination Products
# Bydureon Bcise (exenatide)
# Ozempic (semaglutide)
# Rybelsus (semaglutide) tablets
# Soliqua (insulin glargine and lixisenatide)
# Xultophy (insulin degludec and liraglutide)
# Adlyxin (lixisenatide)
# Effective 11/01/2022

| | | | |
|---|---|---|---|
| **Plan** | ☐ MassHealth<br>☒ MassHealth (PUF)<br>☐Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☒ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit (NLX) | | |
| **Specialty Limitations** | N/A | | |
| **Contact Information** | **Specialty Medications** | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | **Non-Specialty Medications** | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | **Medical Specialty Medications (NLX)** | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| **Exceptions** | N/A | | |

## Overview

Glucagon-like peptide-1 (GLP-1) receptor agonist act on the same receptor as the endogenous hormone incretin, which increases glucose-dependent insulin secretion, decreases inappropriate glucagon secretion, and slows gastric emptying. Increases first- and second-phase insulin secretion.

| No PA | PA required |
|---|---|
| Bydureon® (exenatide extended-release pen) | Bydureon BCise® (exenatide extended-release auto-injection) |
| Byetta® (exenatide) § | Ozempic® (semaglutide injection) |
| Trulicity® (dulaglutide) [PD] | Rybelsus® (semaglutide tablet) |
| Victoza® (liraglutide) | Soliqua® (insulin glargine/lixisenatide) |
| | Xultophy® (insulin degludec/liraglutide) |
| | Adlyxin® (lixisenatide) |

[PD] Preferred Drug. A trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Trulicity® (dulaglutide) and GLP-1 receptor agonists, a trial with a preferred agent is not required prior to approval of a non-preferred agent.

§ Brand Preferred over generic equivalents. In general, requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

## Coverage Guidelines

Authorizations requests will be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member has a diagnosis of Type 2 Diabetes Mellitus †
2. **ONE** of the following:
    a. Prescriber documented inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with **ONE** of the following:
        i. Bydureon (exenatide extended-release pen)
        ii. Byetta(exenatide)
        iii. Trulicity (dulaglutide)
        iv. Victoza (liraglutide)
    b. **BOTH** of the following:
        i. Prescriber documented adverse reaction or contraindication to metformin
        ii. Prescriber documented inadequate response (defined as at least 90 days of therapy within a 120-day time period) to **ONE** of the following:
            1. Bydureon (exenatide extended-release pen)
            2. Byetta (exenatide)
            3. Trulicity (dulaglutide)
            4. Victoza (liraglutide)
    c. **BOTH** of the following:
        i. Prescriber documented of an inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin
        ii. Prescriber documented of an adverse reaction to **ONE** of the following:
            1. Bydureon (exenatide extended-release pen)
            2. Byetta (exenatide)
            3. Trulicity (dulaglutide)
            4. Victoza (liraglutide)
    d. **BOTH** of the following:
        i. Prescriber documented inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin
        ii. Contraindication to **ALL** of the following:
            1. Bydureon (exenatide extended-release pen)
            2. Byetta (exenatide)
            3. Trulicity (dulaglutide)
            4. Victoza (liraglutide)
3. If requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing schedule

NOTE: *Requests for Rybelsus® (semaglutide tablet) may be approved in patients without a trial of a GLP-1 agonist if it is documented that the member is not a candidate for injectable formulations (including documentation of needle phobia) and if an alternative second line agent is used in combination with metformin (e.g., DPP-IV, SGLT2, TZD, sulfonylurea or insulin) in place of the GLP-1 agonist in 2a to 2c above.*

*† For requests for Adlyxin® (lixisenatide), Bydureon BCise® (exenatide extended-release auto-injection), Ozempic® (semaglutide injection), or Rybelsus® (semaglutide tablet), prediabetes may be accepted as an appropriate diagnosis if all other criteria are met.*

## Limitations

1. Initial approval and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

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|---|---|
| Bydureon Bcise | 4 autoinjectors per 28 days |
| Adlyxin 10/20mcg starter pack, 20mcg/0.2mL | 2 pens per 28 days |
| Ozempic 2mg/1.5mL | 2 pens per 28 days |
| Ozempic 4mg/3mL | 1 pen per 28 days |
| Ozempic 8mg/3mL | 1 pen per 28 days |
| Soliqua | 6 prefilled pens per 30 days |
| Rybelsus | 30 tablets per 30 days |
| Xultophy | 1 carton (5 prefilled) pens per 30 days |

## Appendix

**Appendix A: Brand Preferred over Generic**

In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are Brand Name Preferred Over Generic

- exenatide

## References


1. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; September 2020.
2. Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; January 2020.
3. Bydureon (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2020.
4. Bydureon BCise (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2020.
5. Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2020.
6. Soliqua (insulin glargine/lixisenatide) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; December 2020.
7. Xultophy (insulin degludec and liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2019.
8. Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2020.
9. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; April 2021


## Review History

09/30/2020 – Updated; Match Masshealth partial unified formulary requirements for implementation on 1/1/21

05/19/2021 – Updated and Reviewed; References updated; Added Ozempic 4mg/3mL formulation to PA and Limitations to match MH UPPL for 7/1/2021. Effective 07/01/2021.

11/17/2021 – Reviewed and Updated for Nov P&T; Adlyxin® (lixisenatide) added to criteria; include new footnotes to GLP-1 agonists requiring PA to allow for approval of requests for members with prediabetes based on published consensus guideline. Additionally, footnote for GLP-1 agonists was updated to clarify that members with needle-phobia can be reviewed using the same guidance as those with a contraindication to injectable formulations. Effective 1/1/2022
11/16/2022 – Reviewed and updated for Nov P&T. Clarified QLs. Added criteria C: requiring an inadequate response, adverse reaction or contraindication to metformin AND adverse reaction to one of the agents (Bydureon, Byetta, Trulicity, Victoza). Added criteria #3 of quantity limits exceeded. Effective 11/1/2022.

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