

# Drug Therapy Guidelines

Incretin Mimetics – Adlyxin™ (lixisenatide)  
 Bydureon® (exenatide), Bydureon®BCise™  
 (exenatide extended-release) Byetta® (exenatide),  
 Ozempic® (semaglutide), Tanzeum™ (albiglutide),  
 Trulicity™ (dulaglutide), Victoza® (liraglutide)

	<i>Applicable*</i>	
Medical Benefit	x	<b>Effective:</b> 11/8/18
Pharmacy- Formulary 1	x	<b>Next Review:</b> 3/19
Pharmacy- Formulary 2	x	<b>Date of Origin:</b> 11/06
Pharmacy- Formulary 3/Exclusive	x	<b>Review Dates:</b> 11/16/05, 10/15/06, 11/5/07, 12/15/08, 12/09, 6/10, 3/11, 9/11, 9/12, 9/13, 9/14, 3/15, 3/15, 3/16, 3/17, 3/18
Pharmacy- Formulary 4/AON	x	

## I. Medication Description

Incretin mimetics are synthetic analogues of the gut hormone glucagon-like peptide-1 (GLP-1), which enhances glucose-dependent insulin secretion, suppresses glucagon secretion, slows gastric emptying, and promotes beta-cell proliferation.

## II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

## III. Policy

### **Formulary 3/Exclusive: See Sections A and B**

A. Non-preferred medications: Adlyxin, Ozempic, Tanzeum, and Trulicity

Plan-preferred medications: Bydureon, Bydureon BCise, Byetta, and Victoza

B. Coverage of any non-preferred medication can be granted if the following criteria are met:

- When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results **AND**
- Coverage of any non-preferred medication will be provided when the patient has experienced intolerance or therapeutic failure with at least one plan-preferred medication first **OR** when at least ONE of the following criteria are met:
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member's prescription drug regimen.
  - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where "stable" is defined as receiving the medication

for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of "stable).

- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member's adherence or to compliance with the member's plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member's ability to achieve or maintain reasonable functional ability in performing daily activities.

#### IV. Quantity Limitations

- Adlyxin is limited to two prefilled pen devices per 28 days
- Bydureon and Bydureon BCise are limited to four doses per month
- Byetta is limited to one prefilled pen device per month
- Ozempic is limited as follows:
  - 0.25mg and 0.5mg/dose Pre-Filled Pen solution for injection: 1.5mL (1 pen) per 28 days
  - 1mg/dose Pre Filled Pen solution for injection: 3mL (2 pens) per 28 days
- Tanzeum is limited to four prefilled pen devices per month
- Trulicity is limited to four pens or prefilled syringes per month
- Victoza is limited to two prefilled pen devices per month
  - This quantity accommodates up to 1.2 mg daily for 30 days
  - If there is documentation that a trial with Victoza 1.2mg daily does not result in acceptable glycemic control, coverage of 3 prefilled pen devices per month (to accommodate 1.8mg daily for 30 days) will be approved.

#### V. Coverage Duration

Coverage may be granted for 12 months and may be renewed.

#### VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

#### VII. Billing/Coding Information

Pertinent indication: 250.00- type II diabetes mellitus (*E11.9*)

### VIII. Summary of Policy Changes

- 6/1/11:
  - Quantity limits will apply to Byetta
  - Initial quantity limits for Victoza allow for 1.2mg QD; 1.8mg QD coverage requires review
- 12/1/11: Trial with Byetta not required for coverage of Victoza
- 3/2012: Added Bydureon to policy upon FDA-approval
- 6/2012: Extended authorization period
- 12/15/12: no policy changes
- 12/15/13: no policy changes
- 7/7/14: Tanzeum added to policy
- 10/31/14: Trulicity added to policy
- 1/1/15: no policy changes
- 1/15/15: criteria differentiated for Medicaid/Family Health Plus
- 6/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 1/1/16: Trulicity and Tanzeum are plan non-preferred medications on Formulary 3/Exclusive
- 6/15/16: no policy changes
- 12/28/16: Adlyxin added to policy
- 4/5/17: no policy changes
- 5/1/17: step therapy criteria added
- 5/1/18: coverage criteria updated to specify required metformin trial; coverage duration changed to 12 months; Bydureon BCise added to policy
- 6/1/18: Ozempic added to policy
- 11/8/18: removed metformin requirement and confirmation of diagnosis from coverage criteria

### IX. References

1. Product Information: Byetta (exenatide). AstraZeneca Pharmaceuticals, LP. Wilmington, DE 19850. Revised 2/2015.
2. Product Information: Victoza (liraglutide). Novo Nordisk, Inc. Plainsboro, NJ 08536. Revised 8/2017.
3. American Diabetes Association. Position Statement: Standards of Medical Care in Diabetes – 2010. Diabetes Care. 2010 Jan; 33 Suppl 1: S11-61. Available from: [http://care.diabetesjournals.org/content/33/Supplement\\_1/S11.long](http://care.diabetesjournals.org/content/33/Supplement_1/S11.long)
4. Nathan DM, Buse JB, Davidson MB, et al (American Diabetes Association; European Association for the Study of Diabetes). Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy; a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care. 2009.
5. Rodbard HW, Davidson JA, Garber AJ, et al. Statement by an American Association of Clinical Endocrinologists/ American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An algorithm of glycemic control. Endocrine Practice. 2009. Available from: <http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf>
6. Clinical Pharmacology, Accessed 1/2018.

7. Product Information: Bydureon (exenatide extended release). AstraZeneca Pharmaceuticals, LP. Wilmington, DE 19850. Revised 10/2017.
8. Product Information: Tanzeum (albiglutide). GlaxoSmithKline. Wilmington, DE 19808. Revised 12/2017.
9. Product Information: Trulicity (dulaglutide). Eli Lilly and Company. Indianapolis, IN 42685. Revised 8/2017.
10. Product Information: Adlyxin (lixisenatide). Sanofi-Aventis U.S. LLC. Bridgewater, NJ 08807. Revised 7/2016.
11. Product Information: Bydureon BCise (exenatide extended release). AstraZeneca Pharmaceuticals, LP. Wilmington, DE 19850. Revised 12/2017.
12. Product Information: Ozempic (semaglutide). Novo Nordisk. Plainsboro, NJ 08536. Revised 12/2017
13. American Diabetes Association. Standards of medical care in diabetes – 2016. *Diabetes Care*. 2016;39(suppl 1): S1-S106.
14. Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual: Chapter 15. (CMS Publication No. 100-02). Retrieved from <http://www.cms.hhs.gov>.

*\*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.*

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*