I. Medication Description

Incretin mimetics are synthetic analogues of the gut hormone glucagon-like peptide-1 (GLP-1), which works to enhance glucose-dependent insulin secretion and mimic the actions of the several other glucoregulatory hormones known as incretins.

II. Position Statement

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

III. Policy

Medical only: See Sections A and B
Medical with corresponding pharmacy coverage: See corresponding Formulary listing, below.
Formulary 1: See Sections A and B
Formulary 2, 4/AON: See Sections A and B
Formulary 3/Exclusive: See Sections A, B, C, and D

A. Coverage is provided for the treatment of type II diabetes in adults
B. Coverage is provided for members who have failed to achieve desired glucose control despite prior use of at least one oral hypoglycemic medication
C. Non-preferred medications: Adlyxin, Tanzeum, Trulicity
   Plan-preferred medications: Bydureon, Byetta, and Victoza.
D. 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
   • At least one of the following must be met:
     o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
     o 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.
     o 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).

- 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 is limited to four 2mg doses per month
- Byetta is limited to one prefilled pen device per month
- 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 will be granted indefinitely through the life of this policy once the initial criteria are met.

VI. Coverage Renewal Criteria

n/a

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
• 7/1/16: 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

IX. References


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.
Drug Therapy Guidelines | Incretin Mimetics | Last Review Date: 4/2017

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.