

Title: exenatide (Byetta) and liraglutide (Victoza)

Origination:	Revised:	Annual Review: 12/16/10
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Exenatide is the first medication in a new class of drugs called glucagon-like peptide-1 (GLP-1) receptor agonists or incretin mimetics, which works by reducing fasting and post-prandial blood glucose concentrations.
- GLP-1 agonist act by stimulating glucose-dependent insulin secretions, restoring insulin response, lowering glucagons levels during hyperglycemic periods, slowing gastric emptying, and reducing food intake.
- In clinical trials, these drugs showed a significant weights loss in Members.
- GLP-1 agonists are not a substitute for insulin in insulin-requiring Members and should not be used in patients with type I Diabetes Mellitus.
- Byetta and Victoza[®] are indicated for the treatment of patients with type II Diabetes Mellitus as an adjunct to metformin, a thiazolidinedione, and/or a sulfonylurea therapy or as second-line monotherapy.
- Byetta is dosed twice daily, 60 minutes before morning and evening meals. Give the SC injection into thigh, abdomen, or upper arm. Initially 5 mcg twice daily; may increase to 10 mcg twice daily after one (1) month.
- Victoza is dosed once daily, without regard to meals. Give the SC injection into thigh, abdomen, or upper arm. Initially 0.6 mg one (1) daily for one (1) week; may increase to 1.8 mg once daily if needed.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- **Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.**

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Procedure:

- 1.0 Request for *initial therapy* with Byetta or Victoza for type II Diabetes Mellitus requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 1.1 Member's plan includes injectable medication coverage;
 - 1.2 Diagnosis of type II Diabetes Mellitus;
 - 1.3 Member has taken metformin, a sulfonylurea and/or a thiazolidinedione in the past 120 days;
 - 1.4 If all criteria are met, therapy may be approved for one (1) year.

References:

1. Byetta® [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; April 2005.
2. Victoza® [package insert]. Princeton, NJ: Novo Nordisk A/S; January 2010.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.