Policies Repository

Independence Blue Cross

Policy Title	Exenatide (Byetta®)
Policy Number	FS.CLIN.43

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Exenatide (Byetta®) is indicated as adjunctive therapy to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus.

The use of exenatide (Byetta®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Exenatide (Byetta®) is an incretin mimetic agent; that is, it mimics the actions of naturally occurring incretins such as glucagon-like peptide-1 (GLP-1), causing the enhancement of glucose-dependent insulin secretion and exhibiting other antihyperglycemic actions. In vitro, exenatide (Byetta®) binds and activates human GLP-1 receptors, increasing the glucose-dependent synthesis of insulin and secretion of insulin from pancreatic beta cells.

In the presence of elevated glucose concentrations, exenatide (Byetta®) promotes insulin secretion from beta cells.

Policy Guideline Inclusion

Exenatide (Byetta®) is approved when all of the following inclusion criteria are met:

- Documentation of type 2 diabetes mellitus
- Documentation of a trial and failure of one or contraindication to all of the following:
  - A metformin-containing product
  - A thiazolidinedione
  - A sulfonylurea

Policy Guideline Exclusion

Exenatide (Byetta®) is denied when any of the following exclusion criteria are present:

- No documentation of type 2 diabetes mellitus
- No documentation of a trial and failure of one or contraindication to all of the following:
  - A metformin-containing product
  - A thiazolidinedione
  - A sulfonylurea

Policy List of Applicable Drugs

Brand Name	Generic Name
Byetta	exenatide

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Byetta® (exenatide injection) [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; 2007. Also available online at: http://pi.lilly.com/us/byetta-pi.pdf. Accessed October 14, 2010.

DeFronzo RA, Ratner RE, Han J, et al. Effects of exenatide (exendin-4) on glycemic control and

weight over 30 weeks in metformin-treated patients with type 2 diabetes. *Diabetes Care*. 2005;28(5):1092-1100.

Degn KB, Brock B, Juhl CB, et al. Effect of intravenous infusion of exenatide (synthetic exendin-4) on glucose-dependent insulin secretion and counterregulation during hypoglycemia. *Diabetes*. 2004;53(9):2397-2403.

Fineman MS, Bicsak TA, Shen LZ, et al. Effect on glycemic control of exenatide (synthetic exendin-4) additive to existing metformin and/or sulfonylurea treatment in patients with type 2 diabetes. *Diabetes Care*. 2003;26(8):2370-2377.

Nathan DM, Buse JB, Davidson MB, et al. Medical Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care* 2008 (Dec);31:1-11.

Policy Link to Related Policies

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