

Pharmacy Policy Bulletin

Title: Exenatide (Byetta®)

Policy #: 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 restrictions. 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. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. 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.

Intent

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 (i.e. clinical pharmacy and/or Medical Director review).

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

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

Guidelines

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References

Byetta® (exenatide injection) [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; 2011. Also available online at: <http://pi.lilly.com/us/byetta-pi.pdf>. Accessed October 27, 2011.

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.

Applicable Drugs

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Strength and/or formulation
Exenatide (Byetta)	All

Cross References

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