Policies Repository

Independence Blue Cross

Policy Title	Exenatide (Byetta®)
Policy Number	FS.CLIN.25

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 improve glycemic control in individuals with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione but have not achieved adequate glycemic control. 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. In two multicenter, triple-blinded, placebo-controlled trials, exenatide (Byetta®) showed a clinically significant reduction in glycosylated hemoglobin (HbA1c) (one trial compared the adjunct use of exenatide [Byetta®] with a placebo in individuals who were taking metformin and the other compared the adjunct use of exenatide [Byetta®] with a placebo in individuals who were taking metformin and/or sulfonylurea).

Policy Guideline Inclusion

Exenatide (Byetta®) is approved when the following inclusion criterion is met:

- Documentation of type 2 diabetes mellitus with concurrent use of one of the following:
  - Metformin
  - A sulfonylurea
  - A thiazolidinedione

Policy Guideline Exclusion

Exenatide (Byetta®) is denied when the following exclusion criterion is present:

- No documentation of type 2 diabetes mellitus with concurrent use of one of the following:
  - Metformin
  - A sulfonylurea
  - A thiazolidinedione

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 August 4, 2008.

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.

Policy Link to Related Policies

Printed 11/11/2008 15:19:32

constitute a contract. If you are an IBC member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. IBC does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of IBC. If you have a specific medical condition, please consult with your doctor. IBC reserves the right at any time to change or update its Policy Bulletins.