



Prior Authorization Approval Criteria

Byetta (exenatide)

Generic name:	Exenatide
Brand name:	Byetta
Medication class:	Antidiabetic agent
FDA-approved uses:	Indicated as adjunctive therapy to improve glycemic control in patients 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.
Available Dosage Forms:	1.2 ml (5 mcg/dose) and 2.4 ml (10 mcg/dose) prefilled pens, 60 doses each, for injection
Usual dose range:	5 mcg subcutaneously (sq) taken twice daily within an hour before the morning and evening meal. May be increased to 10 mcg sq after one month.
Duration of therapy:	Indefinite
Cost (based on AWP 2008):	1.2 ml prefilled pen = \$210.38; 2.4 ml prefilled pen = \$246.88

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Must be receiving ongoing care under the guidance of a health care provider skilled in the use of insulin and supported by the services of a diabetes educator.
- Patient must be a Type II diabetic.
- Must be taking metformin, a sulfonylurea, or thiazolidinedione. (May take a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione. However, combination of sulfonylurea and thiazolidinedione has not been studied, therefore it is not recommended.)
- Has not achieved adequate glycemic control despite current treatment.

Cautions:

- Not recommended for patients with ESRD, severe renal impairment, or severe gastrointestinal disease.
- Patient using Byetta with D-phenylalanine derivatives, meglitinides, or alpha-glucosidase inhibitors has not been studied and is generally not recommended.

Contraindications:

- Known hypersensitivity to exenatide or any of its components.

Not approved if:

- Patient has any contraindications to the use of exenatide
- Patient does not meet the above-stated criteria
- Patient has type 1 diabetes
- Patient is using insulin

Special considerations:

- Not a substitute for insulin in insulin-requiring patients.
- Not intended to be given with insulin.
- Mimics natural physiology by enhancing insulin secretion only in the presence of hyperglycemia; insulin secretion decreases as blood glucose concentrations approach normal.
- Along with improvements in HbA1c, most patients lost weight in clinical trials.
- 30-day prefilled pens (5 mcg and 10 mcg per dose)
- Store in fridge.
- Antiemetics don't work for nausea.
- Nausea upon initiation of therapy.
- Byetta use with insulin, D-phenylalanine derivatives, meglitinides, or alpha-glucosidase inhibitors is not recommended since it has not been studied.
- When Byetta is added to metformin, the current dose of metformin can be continued.
- When added to a sulfonylurea, reduction in dose of the sulfonylurea should be considered due to risk of hypoglycemia.

Step therapy requirements:

- 2 different antidiabetic agents (metformin, sulfonylurea, thiazolidinedione, insulin)

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 10/12/05

First revision: 3/14/07

Second revision: 1/08/08