

Pharmacy Policy Bulletin

Title: Pramlintide (Symlin®/SymlinPen®)

Policy #: Rx.01.73

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 regularly 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:

Pramlintide (Symlin®/SymlinPen®) is indicated as adjunct therapy for individuals with type 1 or type 2 diabetes who are currently receiving optimal insulin therapy but have failed to achieve desired glycemic control. Individuals with type 2 diabetes may be taking a sulfonylurea agent and/or metformin with insulin or insulin alone.

The use of pramlintide (Symlin®/SymlinPen®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

▶ Description:

Pramlintide (Symlin®/SymlinPen®) is a synthetic analog of the naturally occurring beta-cell hormone amylin. Amylin is co-secreted with insulin by beta cells in response to meals, and it aids in the regulation of glucose levels. Pramlintide (Symlin®/SymlinPen®) works by slowing gastric emptying, decreasing post-prandial glucagon secretion, and inducing weight loss.

▶ Policy:

Pramlintide (Symlin®/SymlinPen®) is approved when **one** of the following inclusion criteria is met:

- Documentation of type 1 diabetes with concurrent insulin therapy
- Documentation of type 2 diabetes with concurrent insulin therapy

▶ 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 services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ References:

Buse JB, Weyer C, Maggs DG. Amylin replacement with pramlintide in type 1 and type 2 diabetes: a physiological approach to overcome barriers with insulin therapy. *Clinical Diabetes*. (serial online). [Clinical Diabetes Web site].


2002;20(3):137-144. Available at: <http://clinical.diabetesjournals.org/cgi/content/abstract/20/3/137>. Accessed April 8, 2011

Heptulla RA, Rodriguez LM, Bomgaars L, Haymond MW. The role of amylin and glucagon in the dampening of glycemic excursions in children with type 1 diabetes. *Diabetes*. 2005;54(4):1100-1107.

Riddle MC, Drucker DJ. Emerging therapies mimicking the effects of amylin and glucagon-like peptide 1. *Diabetes Care*. 2006;29(2):435-449.

Symlin® (pramlintide) [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc; 2005. Also available online at: <http://www.symmlin.com>. Accessed April 8, 2011

Applicable Drugs:

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

Brand Name	Generic Name
Symlin/ SymlinPen	pramlintide

Cross References:

Policy Version Number: 1.00
P&T Approval Date: March 08, 2012
Policy Effective Date: June 01, 2012
Next Required Review Date: March 08, 2013

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