

Clinical Policy: Pramlintide (Symlin)

Reference Number: PA.CP.PMN.129

Effective Date: 10.17.18

Last Review Date: 01.19

[Revision Log](#)

Description

Pramlintide (Symlin®) is an amylin analog.

FDA Approved Indication(s)

Symlin is indicated for patients with type 1 or type 2 diabetes who use mealtime insulin and have failed to achieve desired glycemic control despite optimal insulin therapy.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Symlin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diabetes Mellitus (must meet all):

1. Diagnosis of type 1 or type 2 diabetes mellitus;
2. Member meets one of the following (a or b):
 - a. Failure of three or more daily mealtime insulin (e.g., Apidra®, Humalog®, Humulin®, Novolog®) injections, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Currently using insulin pump;
3. Dose does not exceed one of the following (a or b):
 - a. For type 1 diabetes: 60 mcg prior to each major meal;
 - b. For type 2 diabetes: 120 mcg prior to each major meal.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Diabetes Mellitus (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by reduction in HbA1c at end of initial authorization period;
3. If request is for a new dose, dose does not exceed one of the following (a or b):
 - a. For type 1 diabetes: 60 mcg prior to each major meal

- b. For type 2 diabetes: 120 mcg prior to each major meal.
Approval duration: 12 months

III. Other diagnoses/indications (must meet 1 or 2):

- Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
Approval duration: Duration of request or 12 months (whichever is less); or
- Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

IV. Diagnoses/Indications for which coverage is NOT authorized:

- Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

V. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HbA1C: hemoglobin A1c

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Apidra® (insulin glulisine)	Individualize dosage	Individualize dosage
Humalog® (insulin lispro)	0.5 to 1 U/kg SC daily	Individualize dosage
Humulin® R (regular insulin human)	0.5 to 1 U/kg SC daily	Individualize dosage
Humulin® N (NPH human isophane)	0.5 to 1 U/kg SC daily	Individualize dosage
Novolog® (insulin aspart)	Individualize dosage	Individualize dosage

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): prior serious hypersensitivity reaction to Symlin or its ingredients; hypoglycemia unawareness; confirmed gastroparesis
- Boxed warning(s): severe hypoglycemia

VI. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Type 1 or type 2 diabetes	1 injection SC prior to each major meal (≥ 250 kcal or containing ≥ 30 g of carbohydrate) <ul style="list-style-type: none"> Type 1 diabetes: start at 15 mcg Type 2 diabetes: start at 60 mcg 	Type 1: 60 mcg/injection Type 2: 120 mcg/injection

VII. Product Availability

- Disposable 1.5 mL multidose pen-injector: 15 mcg, 30 mcg, 45 mcg, 60 mcg
- Disposable 2.7 mL multidose pen-injector: 60 mcg, 120 mcg

VIII. References

1. Symlin Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2016. Available at: www.symlin.com. Accessed November 1, 2018.
2. American Diabetes Association. Standards of medical care in diabetes—2018. Diabetes Care. 2018; 41(suppl 1): S1-S159.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created	10/18	
1Q 2019 annual review: references reviewed and updated.	01/19	