Clinical Policy: Pramlintide (Symlin)

Reference Number: PA.CP.PMN.129
Effective Date: 02/2026
Last Review Date: 01/2026

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 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. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Member meets ONE of the following (a or b):
   a. Failure of daily mealtime insulin of 3 or more insulin products (e.g., Apidra, Humalog, Humulin N, Humulin R, Novolog), each used for ≥ 3 months, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Currently using insulin pump;
5. 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

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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.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 dose increase, new 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

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. 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

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

A. 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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

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

V. 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)	Type 1: 60 mcg/injection

Indication	Dosing Regimen	Maximum Dose
	• Type 1 diabetes: start at 15 mcg • Type 2 diabetes: start at 60 mcg	Type 2: 120 mcg/injection

VI. Product Availability

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

VII. References

1. Symlin Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019. Available at: www.symlinhcp.com. Accessed October 21, 2025.
2. American Diabetes Association. Standards of medical care in diabetes—2025. Diabetes Care. 2025; 48(suppl 1): S1-S352. Accessed November 13, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	Date
Policy created	01/2026