

## Clinical Policy: Pramlintide (Symlin)

Reference Number: CP.HNCA.129

Effective Date: 06.01.18

Last Review Date: 02.19

Line of Business: Commercial - HNCA

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Pramlintide (Symlin<sup>®</sup>) 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 Centene Corporation<sup>®</sup> 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  $\geq$  18 years;
4. Member meets one of the following (a or b):
  - a. Failure of three or more daily mealtime insulin (e.g., Humalog<sup>®</sup>, Humulin<sup>®</sup> N, Humulin<sup>®</sup> R,) injections, each used for  $\geq$  3 months, unless contraindicated or clinically significant adverse effects are experienced;
  - 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: 6 months or to member's renewal period, whichever is longer**

### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Diabetes Mellitus (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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:**

**Commercial – 6 months or to member’s renewal period, whichever is longer**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**IV. 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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**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
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

*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 ( $\geq$ 250 kcal or containing $\geq$ 30 g of carbohydrate) <ul style="list-style-type: none"> <li>• Type 1 diabetes: start at 15 mcg</li> <li>• Type 2 diabetes: start at 60 mcg</li> </ul>	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](http://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: no significant clinical changes from previously approved corporate policy; replaces Medicaid CP.PST.13; split from commercial policy CP.CPA.16; references reviewed and updated.	02.25.18	05.18
1Q 2019 annual review: added requirement for endocrinologist prescriber; references reviewed and updated.	10.12.18	02.19

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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