Clinical Policy: Pramlintide (Symlin)
Reference Number: CP.PST.13
Effective Date: 11/06
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

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See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Pramlintide (Symlin®) is an amylin analog.

FDA approved indication
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 (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Symlin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Electronic Step Therapy for Symlin (must meet all)**:**

~~1. Patient is ≥ 18 years old;~~
~~2. Diagnosis of Type 1 or Type 2 diabetes;~~
~~3.~~1.Previous ~~Concomitant~~ use of mealtime insulin therapy (e.g., Apidra, Humalog, Humulin, Novolin, Novolog, Relion) or an insulin pump ~~as evidenced by pharmacy claims history~~ in the last 30 days~~, or use of insulin pump~~;
~~4.~~2.~~Dosage consistent with FDA dosing guidelines~~Dose does not exceed 120 mcg per injection (1 pen per injection).~~.~~

Approval duration: 6 months

II. Continued Therapy

A. Electronic Step Therapy for Symlin (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. ~~Evidence of adherence to treatment regimen, including concomitant~~ Current use of mealtime insulin therapy or an insulin pump ~~as evidenced by pharmacy claims history~~;

~~3.~~ If request is for a dose increase, new dose does not exceed 120 mcg per injection (1 pen per injection)~~.~~
~~4.~~3.~~Dosage consistent with FDA approved dosing guidelines~~.

Approval duration: 6 months

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Symlin	1 injection subcutaneously prior to each major meal (≥ 250 kcal or containing ≥ 30 g of carbohydrate)	120 mcg/injection

V. Product Availability

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

VI. Workflow Document

CP.PST.13
Pramlintide (Symlin)

Field Code Changed

VII. References

1. Symlin® Pprescribing iInformation. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2015. Available at: www.symlin.com. Accessed ~~February 2016~~January 11, 2017.
~~1.~~2. American Diabetes Association. Standards of medical care in diabetes—2017. Diabetes Care. 2017; 40(suppl 1): S1-S133.
~~2. Symlin® monograph, *Clinical Pharmacology*. Accessed February 2016, http://www.clinicalpharmacology.com.~~
~~3. Diabetes Mellitus, Type 2: Treatment & Medication, monograph from eMedicine. Accessed February 2016. http://emedicine.medscape.com/article/117853-overview~~
~~4. Diabetes Mellitus, Type 1: Treatment & Medication, monograph from eMedicine. Accessed February 2016. http://emedicine.medscape.com/article/117739-overview~~
~~5. Dungan K. Amylin analogs for the treatment of diabetes mellitus. Hirsch IB. (Ed). UpToDate. Waltham MA. Accessed February 2016~~

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added "SymlinPen 60 mcg, 120 mcg (subject to pen device approval protocols)" to the "Brand" section. Omitted the following at the beginning of the "Criteria for Approval" section: "**Note:** This drug should be prescribed by or in consultation with a specialist in endocrinology". Added the following items to the "Criteria for Approval" "Type 1 Diabetes" section: ▪ Prescribed by or in consultation with a specialist in endocrinology Age ≥ 18 years	11/09	11/09

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added the following items to the "Criteria for Approval" "Type 2 Diabetes" section: ▪ Prescribed by or in consultation with a specialist in endocrinology ▪ Age ≥ 18 years ▪ Patient has tried and failed combination metformin with sulfonylurea and metformin with thiazolidinedione (TZD) therapy, unless contraindicated. Contraindications include intolerance to or adverse reactions to any of the combination components or comorbidities, other than obesity, precluding their use and ▪ Patient is compliant with oral therapy or Patient is compliant with insulin therapy Added "Symlin® should not be administered to patients taking Metoclopramide due to possible antagonism to effects of Pramlintide" to the "Special Instructions" section. Updated Reference section to reflect current literature search and reference documents.		
Added combination metformin and DPP-IV inhibitors (along with other combos) as an oral therapy precondition, with an "or" statement. Specified the approval of Symlin is for use of the vials. Updated Reference section to reflect current literature search and reference documents.	10/10	10/10
Added "from pancreatic beta cells, and reduces postprandial increases in glucose" to the "Description" section. Removed the requirement for combination oral and insulin therapy and three or more daily insulin injections. Changed oral therapy options from "OR" statements to "AND" statements. Updated Reference section to reflect current literature search and reference documents	11/11	11/11
Revised Symlin's Description and included its mechanism of action. Combined age and diagnosis requirement in criteria for approval Revised HbA1c requirement in criteria for approval Inserted maximized dose requirement for Type 2 DM oral therapy in criteria for approval. Removed compliance with Type 2 DM oral therapy requirement in criteria for approval	11/12	11/12

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Edited Type 2 DM insulin requirement criteria for approval to match Type 1 DM criteria. Reiterated insulin requirement in Special Instructions. Added dose titration recommendation for hypoglycemia precaution in Special Instructions. Added drug interaction warning with medications that stimulate GI motility in Special Instructions. Added recommendation against off-label use of Symlin with GLP-1 based therapies in Special Instructions. Added Amylin Analogs Up-to-date reference. Removed Metoclopramide drug interaction warning in Special Instructions. Updated references. Added eMedicine Type 1 DM web link.		
Updated Reference section to reflect current literature search and reference documents. Removed the following requirement in the criteria for approval for both Type 1 and Type 2 Diabetes Mellitus for "Prescribed by or in consultation with a specialist in endocrinology."	11/13	11/13
Modified to become step therapy. Removed Sulfonylurea requirement from step. Updated criteria to allow for claims evaluation vs manual review.	11/14	11/14
Converted into new policy template. Combined Type 1 and Type 2 criteria; removed basal insulin and metformin trials for type I and type 2, respectively from step; modified pharmacy look back of meal time insulin to past 30 days to ensure concomitant use; removed look back for test strips claims; removed A1c requirement for type 2. Background: revised to include FDA labeled indication per PI Updated references to reflect current literature search.	02/16	05/16
~~No clinical changes to criteria~~ - Converted to new template - Removed age requirement (age is not an absolute contraindication per PI) per updated template - Removed verification of diagnosis and requirement for demonstrated adherence upon re-auth since this is a step therapy guideline - Added additional examples of mealtime insulin	03~~1~~/17	05/17

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.

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.