POLICY AND PROCEDURE

POLICY TITLE: **Symlin (Pramlintide Acetate) Step Therapy**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2003***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Symlin (Pramlintide Acetate).

Symlin (Pramlintide Acetate) is indicated for:

- Treatment of patients with type 1 diabetes as an adjunctive treatment to mealtime insulin and who have failed to achieve desired glucose control despite optimal insulin therapy
- Treatment of patients with type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Symlin (Pramlintide Acetate), is subject to the prior authorization process.

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PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective header:

- The criterion for automatic coverage of pramlintide acetate (Symlin) is as follows:
  - Must have documented pharmacy claim history for insulin in the past 3 months

- For members without a prior claim history of pramlintide acetate (Symlin), a medical necessity review is completed, and the following criteria must be met:
  - Must have a diagnosis of type 1 or 2 diabetes mellitus and currently be using mealtime insulin
  - Must have a hemoglobin-A1C (HbA1C) level less than or equal to 9%
  - Must have verification from the prescribing physician that member is compliant with self-monitoring of blood glucose and aware of hypoglycemia risk since proper patient selection is crucial to verify the safe and effective use of this medication

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Limits	
Symlin (pramlintide)	4 vials/pens per month

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Symlin [Product Information]. Amylin Pharmaceuticals. San Diego, CA. 2005.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	**DATE APPROVED**
Annual Review	*02/17, 02/18*

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