Original Effective Date: 05/01/2013
Current Effective Date: 05/31/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C4957-A

Symlin (pramlintide)

PRODUCTS AFFECTED

Symlin Pen (pramlintide)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Type 1 or Type 2 Diabetes Mellitus

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. DIABETES MELLITUS:
1. Documentation of diagnosis of Type 1 or Type 2 Diabetes Mellitus
   AND
2. Documentation of HbA1C < 9%

AND

3. Documented adequate trial (3 months) and failure of optimal mealtime insulin therapy or use of insulin pump
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Symlin (pramlintide) include: Prior serious hypersensitivity reaction to Symlin or its ingredients, Hypoglycemia unawareness, Confirmed gastroparesis]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history
   AND
2. Documentation of reduction in A1c (hemoglobin A1c) since starting therapy
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified endocrinologist or diabetes specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Type 1 Diabetes: Maximum 60 mcg before major meals
Type 2 Diabetes: Maximum 120 mcg before major meals

Maximum Quantity Limits – 1 box per 30 days (Symlin Pen 60 #3/30 days or Symlin Pen 120 #5.4/30 days)

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous

DRUG CLASS:

Antidiabetic- Amylin analogs

FDA-APPROVED USES:

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

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Symlin (pramlintide) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Symlin (pramlintide) include: prior serious hypersensitivity reaction to Symlin or its ingredients, hypoglycemia unawareness, confirmed gastroparesis.

OTHER SPECIAL CONSIDERATIONS:
Symlin (pramlintide) has a black box warning for severe hypoglycemia.

Symlin dosage differs depending on whether the patient has type 1 or type 2 diabetes. When initiating therapy with Symlin, initial insulin dose reduction is required in all patients (both type 1 and type 2) to reduce the risk of insulin-induced hypoglycemia. As this reduction in insulin can lead to glucose elevations, patients should be monitored at regular intervals to assess Symlin tolerability and the effect on blood glucose, so that individualized insulin adjustments can be initiated. If Symlin therapy is discontinued for any reason (e.g., surgery or illnesses), the same initiation protocol should be followed when Symlin therapy is re-instituted.
Agents other than pramlintide are currently recommended to treat diabetes mellitus in pregnancy (ADA 2023).

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
SymlinPen 60 SOPN 1500MCG/1.5ML
SymlinPen 120 SOPN 2700MCG/2.7ML

REFERENCES

1. Symlin (pramlintide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019.
2. Standards of Medical Care in Diabetes-2016: American Diabetes Association (ADA). Diabetes Care January 2016; 39(Supplement1).
3. American Diabetes Association (ADA). Diabetes Care. 2019;42(suppl 1):S1-S193. http://care.diabetesjournals.org/content/42/Supplement_1.
4. American Diabetes Association (ADA): American Diabetes Association. 7. Diabetes Technology:

Standards of Medical Care in Diabetes-2022. Diabetes Care 2022; 45:S97-S112.
5. Garber A, Barzilay J, Bloomgarden Z, et al. American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2016. Endocr Pract. 2016; 22:84-113.
6. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical Practice Guidelines for developing a diabetes mellitus comprehensive care plan. Endocr Pract. 2015; 21(Suppl 1):1- 87.
7. Standards of Care in Diabetes – 2023. (2023, January). Retrieved February 15, 2023, from https://diabetesjournals.org/care/issue/46/Supplement_1
8. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2024. Diabetes Care 2024; 47 (Suppl. 1): S158-S178. https://doi.org/10.2337/dc24-S009

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Quantity FDA-Approved Uses References	Q2 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q2 2023
REVISION- Notable revisions: Required Medical Information References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file