Symlin Step Therapy with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
07-01-2024	07-01-2019

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Symlin® (pramlintide) Subcutaneous injection	Adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

The American Diabetes Association Standards of Medical Care in Diabetes recommend the following therapy for type 1 diabetes mellitus:

- Most individuals with type 1 diabetes should be treated with multiple daily injections of prandial and basal insulin, or subcutaneous insulin infusion
- Most individuals with type 1 diabetes should use rapid-acting insulin analogs to reduce hypoglycemia risk.
- Individuals with type 1 diabetes should receive education on how to match mealtime insulin doses to carbohydrate intake, fat and protein content, and anticipated physical activity.(2)

For type 2 diabetes mellitus, the American Diabetes Association recommends the following:

- First-line therapy depends on comorbidities, patient-centered treatment factors, and management needs and generally includes metformin and comprehensive lifestyle modification
- The early introduction of insulin should be considered if there is evidence of ongoing catabolism, if symptoms of hyperglycemia are present, or when A1C levels or blood glucose levels are very high
- A patient-centered approach should guide the choice of pharmacological agents. Consider the effects on cardiovascular and renal comorbidities, efficacy, hypoglycemia risk, impact on weight, cost and access, risk for side effects, and patient preferences.(2)

Many patients with type 2 diabetes eventually require and benefit from insulin therapy.(2) Because the hallmark of type 1 diabetes is absent or near-absent β-cell function, insulin treatment is essential for individuals with type 1 diabetes. Pramlintide is based on the naturally occurring β-cell peptide amylin and is approved for use as an adjunct to insulin treatment in adults with type 1 or type 2 diabetes.(1,2)

REFERENCES

Number	Reference
1	Symlin prescribing information. AstraZeneca Pharmaceuticals, Inc. December 2019.
2	American Diabetes Association. Pharmacologic Approaches to Glycemia Treatment: Standards of Medical Care in Diabetes-2022. Available at: https://care.diabetesjournals.org/content/45/Supplement_1

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Symlinpen 120 ; Symlinpen 60	pramlintide acetate pen-inj	1500 MCG/1.5ML ; 2700 MCG/2.7ML	M ; N ; O	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Symlinpen 120	Pramlintide Acetate Pen-inj 2700 MCG/2.7ML (1000 MCG/ML)	2700 MCG/2.7 ML	4	Pens	30	DAYS			
Symlinpen 60	Pramlintide Acetate Pen-inj 1500 MCG/1.5ML (1000 MCG/ML)	1500 MCG/1.5 ML	4	Pens	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Symlinpen 120 ; Symlinpen 60	pramlintide acetate pen-inj	1500 MCG/1.5ML ; 2700 MCG/2.7ML	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Symlinpen 120	Pramlintide Acetate Pen-inj 2700 MCG/2.7ML (1000 MCG/ML)	2700 MCG/2.7ML	Medicaid
Symlinpen 60	Pramlintide Acetate Pen-inj 1500 MCG/1.5ML (1000 MCG/ML)	1500 MCG/1.5ML	Medicaid

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agents will be approved when ONE of the following is met: 1. The patient has been treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient is currently being treated with the requested agent in the past 90 days AND is at risk if therapy is changed **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The patient's medication history includes use of insulin **OR** 5. The prescriber has stated that the patient has tried insulin therapy AND ONE of the following: A. Insulin therapy was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin therapy **OR** 6. The patient has an intolerance or hypersensitivity to insulin therapy **OR** 7. The patient has an FDA labeled contraindication to ALL insulin therapy **OR** 8. The prescriber has provided documentation that ALL insulin therapy is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of approval:** up to 12 months