

**Symlin Pen® (pramlintide)**  
Effective 04/17/19

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### Overview

SymlinPen is indicated as an 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.

### Coverage Guidelines

Authorization may be granted when the following criteria are met:

- The patient has been receiving SymlinPen 60 or 120 for at least 3 months **AND**
  - The patient has demonstrated an expected reduction in HbA1c since starting the therapy.
- OR**
- The patient does not have any of the following:
    - recurrent severe hypoglycemia that required assistance during the past 6 months
    - gastroparesis
    - patient requires drug therapy to stimulate gastrointestinal motility
    - hypoglycemia unawareness (e.g., inability to detect and act upon the signs or symptoms of hypoglycemia)
    - an HbA1c level greater than 9 percent
- AND**
- The patient is currently receiving optimal mealtime insulin therapy **AND**
  - The patient has experienced an inadequate treatment response to insulin **AND**
  - The patient has a diagnosis of type 1 or type 2 diabetes mellitus

### Rationale

- The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

SymlinPen 60 and 120 is indicated as an 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.

- Clinical guidelines for the management of hyperglycemia in type 2 diabetes issued by the American Diabetes Association (ADA) indicate that an HbA1c of greater than 7% serves as a call to action. Lowering A1c to approximately 7% or less has been shown to reduce microvascular complications of diabetes, and, if implemented soon after the diagnosis of diabetes, it is associated with long-term reduction in macrovascular disease. Therefore, a reasonable A1c goal for many nonpregnant adults is <7%. While the American Diabetes Association Standards of Medical Care in Diabetes recommends lowering the A1C to less than 7% in most patients, some patients may benefit from less stringent A1c goals. A less stringent an A1c goal (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. However, providers might reasonably suggest more stringent A1c goals (such as <6.5%) for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients may include those with short duration of diabetes, type 2 diabetes treated with lifestyle or metformin only, long life expectancy, or no significant cardiovascular disease.<sup>5</sup>
- The American Diabetes Association reports that because A1c is thought to reflect average glycemia over several months, and has strong predictive value for diabetes complications, A1c testing should be performed routinely in all patients with diabetes, at initial assessment and as part of continuing care. Measurement approximately every 3 months determines whether the patient's glycemic targets have been reached and maintained.<sup>5</sup> Therefore, continued use of SymlinPen 60 and 120 will be approved for patients who have demonstrated an expected reduction in HbA1c since starting Symlin therapy for at least three months.

### Limitations

1. Authorizations will be granted for 36 months

### References

1. Symlin (pramlintide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2016 AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed July 2015.
2. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed July 2015.
3. Rodbard HW, Jellinger PS, Davidson JA, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 diabetes mellitus: an algorithm for glycemic control. *Endoc Pract* 2009;15:540-59.
4. Standards of Medical Care in Diabetes—2015. *Diabetes Care* January 2015 38:Supplement 1 S1-S91.
5. Inzucchi S., Buse JB, Bergenstal R, et al. Management of hyperglycemia in type 2 diabetes: A Patient-Centered Approach: a consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2012 Jun;35(6):1364-79. Epub 2012 Apr 19.



6. Handelsman Y, Mechanick, J, Blonde, L, et al. AACE Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan. Endoc Pract. Vol. 17. (Supplement 2).March/April 2011.
7. American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2013 Consensus Statement - Executive Summary. Endoc Pract 2013 May-Jun;19(3):536-57.

### **Review History**

04/00/17 – Reviewed

04/17/19 – Reviewed

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