



# Antidiabetics – Amylin Analogs

## WA.PHAR.33 Antidiabetics Amylin Analogs

### Background:

Pramlintide is an amylin analog designed 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. Amylin is a 37-amino acid peptide that is stored in pancreatic beta cells, is co-secreted with insulin, and has a similar plasma kinetic profile. It affects glucose control through several mechanisms, including slowed gastric emptying, regulation of postprandial glucagon, and reduction of food intake. Glucose influx is better regulated, allowing exogenous insulin therapy to more easily match physiologic needs. Pramlintide is dosed before major meals and titrated as tolerated. Pramlintide has an anorexic effect and carries a black box warning for risk of severe hypoglycemia.

### Medical necessity

| Drug                              | Medical Necessity  |
|-----------------------------------|--|
| Pramlintide (SYMLIN®, SYMLINPEN®) | Pramlintide may be considered medically necessary when:<br>Used for the treatment of type 1 or type 2 diabetes with mealtime insulin and have failed to achieve desired glycemic control despite optimal insulin therapy |

### Clinical policy:

| Drug                              | Clinical Criteria (Initial Approval)   |
|-----------------------------------|--|
| Pramlintide (SYMLIN®, SYMLINPEN®) | Symlin may be covered when <b>ALL</b> of the following are met: <ol style="list-style-type: none"> <li>1. Diagnosis of Type 1 or Type 2 diabetes</li> <li>2. Failed to achieve desired glycemic control despite optimal insulin therapy</li> <li>3. Currently receiving optimal mealtime insulin or continuous insulin infusion (insulin pump)</li> <li>4. <b>NONE</b> of the following:               <ol style="list-style-type: none"> <li>a. Diagnosis of gastroparesis or requiring medication to stimulate gastrointestinal motility (i.e. metoclopramide or erythromycin)</li> <li>b. Hypoglycemia unawareness (e.g., inability to detect and act upon the signs or symptoms of hypoglycemia)</li> <li>c. Poor compliance with current insulin regimen</li> <li>d. Poor compliance with self-blood glucose monitoring</li> <li>e. HbA1C (hemoglobin A1c) level greater than (&gt;) 9% within the last 3 months</li> </ol> </li> </ol> |

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|--|---|
|  | f. Recurrent severe hypoglycemia that required assistance during the past 6 months  |
|  | <b>Approve for 6 months</b>   |
|  | <b>Criteria (Reauthorization)</b>   |
|  | Symlin may be continued when <b>ALL</b> of the following are met:<br>1. Currently receiving optimal mealtime insulin or continuous insulin infusion (insulin pump)<br>2. Documentation of positive clinical benefit |
|  | <b>Approve for 12 months</b>  |

## Dosage and quantity limits

| Drug Name      | Dose and Quantity Limits     |
|----------------|------------------------------|
| Symlin vial    | #4 vials (20mL) per 28-days  |
| SymlinPen® 60  | #4 pens (6mL) per 28-days    |
| SymlinPen® 120 | #4 pens (10.8mL) per 28-days |

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