Prior Authorization Criteria for Pramlintide (Symlin®)

Pramlintide (Symlin) is indicated for:

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

Pramlintide is not intended for all patients with diabetes. Pramlintide should only be used by patients who have not reached their blood glucose goals despite managing their insulin therapy, physical activity, and diet well, monitoring blood glucose as directed, and following-up with their providers on a regular basis. Patients using pramlintide must understand how to adjust pramlintide and insulin doses and be able to recognize hypoglycemia.

Pramlintide is used with insulin to improve blood sugar control after meals. There is an increased risk of insulin-induced severe hypoglycemia with the combination of insulin and pramlintide, particularly in patients with type 1 diabetes and usually within 3 hours following a pramlintide injection. Doses of insulin must be adjusted when pramlintide therapy is started, changed, or stopped. Pramlintide is not indicated for use in pediatric patients.

Pramlintide is given by subcutaneous injection immediately prior to each major meal (≥250 kcal or containing ≥30 g of carbohydrate). In order to administer pramlintide using an insulin syringe, patients must use the dose conversion chart in the package insert. The dose is adjusted based on clinical response and the occurrence of adverse effects. Pramlintide should not be mixed in the same syringe with any type of insulin.

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee for Pramlintide (Symlin) obtained through the TRICARE Mail Order Pharmacy or from a TRICARE retail network pharmacy. This prior authorization does not have an expiration date.

Prior Authorization Criteria for Pramlintide (Symlin)

Coverage is provided for the use of pramlintide as an adjunct treatment in type 1 and type 2 diabetic patients 18 or older who use mealtime insulin therapy and who meet all of the following criteria:

- are currently on mealtime insulin
- have an HbA1c ≤ 9%
- are monitoring blood glucose levels regularly and reliably (3 or more times per day) and are capable of monitoring blood glucose levels pre- and post-meals and at bedtime?
- have failed to achieve adequate control of blood glucose levels despite individualized management of their insulin therapy
- are receiving ongoing care under the guidance of a health care provider skilled in use of insulin and supported by the services of a diabetes educator
Coverage is not provided for patients who:

- have poor adherence to their current insulin regimen or blood glucose monitoring
- have a HbA1c >9%
- have experienced recurrent severe hypoglycemia requiring assistance within the past 6 months
- presence of hypoglycemia unawareness
- have a confirmed diagnosis of gastroparesis or require the use of drugs to stimulate gastrointestinal motility

*Criteria approved through the Uniform Formulary decision-making process*
US Family Health Plan Pramlintide (Symlin®) Prior Authorization Request Form

To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) Mail Order and Retail Pharmacy or through military treatment facilities.

MAIL ORDER and RETAIL

- The provider may call: 1-877-880-7007
- The provider may fax: 1-617-562-5296
- The patient may attach the completed form to the prescription and mail it to: ATTN: Pharmacy, 77 Warren St, Brighton, MA 02135

Prior authorization criteria and a copy of this form are available at: http://www.dmdc.mil/health/managedcare/priorityaccess/form-priorauth.html

**Step 1**

Please complete patient and physician information (Please print)

Patient Name: ____________________________  Physician Name: ____________________________

Address: ________________________________  Address: ________________________________

Sponsor ID #: ____________________________  Phone #: ________________________________

Date of Birth: ____________________________  Secure Fax #: ____________________________

**Step 2**

Please complete the clinical assessment:

1. Does the patient have a confirmed diagnosis of type 1 or type 2 diabetes mellitus? ☐ Yes ☐ No
   - Proceed to Question 2
   - Coverage not approved

2. Has the patient experienced recurrent severe hypoglycemia requiring assistance within the last 6 months OR is the patient typically unaware of the occurrence of hypoglycemia? ☐ Yes ☐ No
   - Proceed to Question 3
   - Coverage not approved

3. Does the patient have a confirmed diagnosis of gastroparesis or does he/she require the use of drugs to stimulate gastrointestinal motility? ☐ Yes ☐ No
   - Proceed to Question 4
   - Coverage not approved

4. Does the patient have a HbA1c ≤ 9%? ☐ Yes ☐ No
   - Proceed to Question 5
   - Coverage not approved

5. Is the patient currently on mealtime insulin? ☐ Yes ☐ No
   - Proceed to Question 6
   - Coverage not approved

6. Is the patient adherent to their current insulin regimen? ☐ Yes ☐ No
   - Proceed to Question 7
   - Coverage not approved

7. Does the patient regularly and reliably monitor blood glucose levels 3 or more times per day and is the patient capable of monitoring blood glucose levels pre- and post-meals and at bedtime? ☐ Yes ☐ No
   - Proceed to Question 8
   - Coverage not approved

8. Has the patient failed to achieve adequate control of blood glucose levels despite individualized management of insulin therapy? ☐ Yes ☐ No
   - Proceed to Question 9
   - Coverage not approved

9. Is the patient under the guidance of a health care provider skilled in use of insulin and supported by the services of a diabetes educator? ☐ Yes ☐ No
   - Coverage approved
   - Coverage not approved

**Step 3**

I certify the above is true to the best of my knowledge. Please sign and date:

Prescriber Signature: ____________________________  Date: ____________________________

Latest revision: 13 April 2011