



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** pramlintide

**Brand Name:** Symlin

**Medication Class:** antidiabetic agent

**FDA Approved Uses:** Type 1 and 2 diabetes mellitus

**Available Dosage Forms:** Injection 0.6mg/ml

**Usual Dose:** Type 1 diabetics:

Initiate at 15mcg subcutaneously to be administered before major meals.  
Titrate in 15 mcg increments to a maintenance dose of 30 or 60 mcg as tolerated every 3 days as long as no clinically significant nausea occurs. Administer before major meals.

Type 2 diabetes:

Initiate at 60mcg subcutaneously to be administered before major meals.  
Titrate up to 120mcg as tolerated every 3-7 days as long as no clinically significant nausea occurs.

**Duration of Therapy:** Indefinite

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- For type 1 diabetes: used as adjunct in patients who use mealtime insulin therapy and have failed to achieve desired glucose control despite optimal insulin therapy.
- Or
- For type 2 diabetes: used as adjunct 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.
  - Failed to achieve adequate glycemic control despite individualized insulin management and are receiving ongoing care under the guidance of a health care professional skilled in the use of insulin and supported by the services of a diabetes educator.
  - Proper patient selection is critical for the safe and effective use of pramlintide. Before initiating therapy, the patients HbA 1c, recent blood glucose monitoring data, history of insulin induced hypoglycemia, current insulin regimen, and body weight should be reviewed.
  - Must be receiving ongoing care under the guidance of a health care provider skilled in the use of insulin and supported by the services of a diabetes educator.

**Cautions:**

- Pramlintide and insulin should never be mixed.
- Insulin dose must be reduced when pramlintide is added to the drug regimen to reduce the risk of insulin induced hypoglycemia. The insulin dosage can then be individualized



based on blood glucose levels associated with the combination therapy.

**Monitoring:**

- Blood glucose and HbA1c levels should be monitored periodically throughout therapy.
- Patients should self-monitor blood glucose before and after meals and at bedtime.

**Contraindications:**

- Hypersensitivity to pramlintide or any of the product ingredients.
- Confirmed diagnosis of gastroparesis.
- Hypoglycemia unawareness.
- Use of other drugs affecting GI motility (anticholinergics, such as atropine) or agents that slow the intestinal absorption of nutrients (alpha glucosidase inhibitors).

**Not Approved if:**

- Patient does not meet the above stated criteria.
- An HbA1c greater than 9%
- Recurrent severe hypoglycemia requiring assistance during the previous 6 months
- Presence of hypoglycemia unawareness
- Confirmed diagnosis of gastroparesis
- Need for medications that stimulate GI motility
- Pediatric patients

**Special Considerations:**

- Pramlintide is not a substitute for insulin but is complementary to the action of insulin.
- Helps lower blood sugar during the first 3 hours after meals.
- Insulin dose must be reduced when initiation pramlintide due to risk of hypoglycemia.
- Patient receiving Pramlintide therapy must be carefully selected and educated regarding the use of this medication and the need for close glucose monitoring.
- Nausea was reported in 1/3 – 1/2 of the patients treated.

Black box warning- increased risk of insulin induced severe hypoglycemia. It does not cause hypoglycemia but it increases the risk of insulin induced severe hypoglycemia.

- Frequent pre- and post-meal glucose monitoring should be conducted and premeal dosages of short acting insulin should be reduced 50%.
- Further insulin dosage adjustments may be necessary in the presence of other substances that lower glucose, including oral antidiabetic agents, ACE inhibitors, disopyramide, fibrates, fluoxetine, MOA inhibitors, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics.
- The FDA has required a Risk Minimization Action Plan (RiskMAP) and a med guide to be distributed to patients receiving pramlintide, in part because of the high risk of hypoglycemia associated with the drug.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_