

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutic Subcommittee.

**Drug:** Symlin® (Pramlintide)

**Class:** Antidiabetic-Amylin

**Formulary medication:** Insulin

**Effective Date:** August 2005

**Policy/Criteria:**

1. Symlin is indicated for:
  - a. Type 1 diabetes mellitus: As an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.
  - b. Type 2 diabetes mellitus: As an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.
2. Only consider pramlintide in patients with insulin-using type 1 or type 2 diabetes who fulfill the following criteria:
  - a. Have failed to achieve adequate glycemic control despite individualized insulin management. A history of HbA1C scores or blood glucose levels must be submitted for evaluation. An HbA1C score of >7% after at least 3 months of optimal therapy can be considered as failure of therapy.
  - b. Are receiving ongoing care under the guidance of a health care professional skilled in the use of insulin and supported by the services of diabetes educators.
3. **DO NOT CONSIDER** patients for pramlintide therapy if they meet any of the following criteria:
  - a. Poor compliance with current insulin regimen
  - b. Poor compliance with prescribed self-blood glucose monitoring
  - c. Have an HbA1c greater than 9%
  - d. Recurrent severe hypoglycemia requiring assistance during the past 6 months
  - e. Presence of hypoglycemia unawareness
  - f. Confirmed diagnosis of gastroparesis
  - g. Require the use of drugs that stimulate GI motility
  - h. Pediatric patients

4. *Discontinue pramlintide therapy if any of the following occur:*
  - a. Recurrent unexplained hypoglycemia that requires medical assistance
  - b. Persistent clinically significant nausea
  - c. Noncompliance with self-monitoring of blood glucose concentrations
  - d. Noncompliance with insulin dose adjustments
  - e. Noncompliance with scheduled health care professional contacts or recommended clinic visits.
5. Pramlintide is considered investigational and is not an FDA-approved indication when used for weight reduction in patients with or without diabetes, and without insulin therapy.

### **Clinical Justification:**

1. Criteria adhere to FDA-approved indication.
2. Pramlintide should not be used as a substitute for insulin.
3. The most common adverse reactions are nausea, vomiting, anorexia, and headache. They appear to be more common than with insulin alone. When used with insulin, pramlintide may cause hypoglycemia, usually within 3 hours of dosing and particularly in patients with type 1 diabetes.
4. Long term safety and efficacy data are not yet available.
5. The safety and efficacy of pramlintide for weight reduction has not been established through clinical trials.

### **Reference:**

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