

## Antidiabetic Agents - SymlinPen (pramlintide acetate)

- Amylin Analog Antidiabetics
- SymlinPen (Pramlintide)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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### Summary

Diabetes mellitus (commonly referred to as diabetes) is a chronic (long-term) medical condition characterized by high blood glucose (sugar). This may be because the pancreas does not make enough insulin (a hormone), or because the body is not responding to insulin the way it should. Insulin helps glucose get into cells in the body, giving it energy. With diabetes, sugar builds up in the blood because

the body stops responding to insulin, or because there is not enough of it. Diabetes is broadly grouped into two types:

- Type 1 diabetes - the pancreas makes no insulin, or a very small amount.
- Type 2 diabetes - cells in the body do not respond to insulin the way it should; sometimes, the pancreas also does not make enough insulin.

Diabetes is usually managed by dietary and lifestyle modifications including exercise, and medications. Medications are used to either control blood sugar, or to lower the chance of complications of diabetes that can happen in the future. These medications can be insulin itself, or medications that help the body make more insulin or help insulin do its job.

Symlin or SymlinPen (pramlintide acetate) is indicated as an adjunctive treatment in those 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. Symlin (pramlintide acetate) is dosed prior to major meals and mealtime insulin is subsequently reduced. As a synthetic analog of human amylin, Symlin or SymlinPen (pramlintide acetate) works by mimicking human amylin which helps reduce postprandial (after mealtime) glucose increases through satiety (feeling full and appetite suppression), slowing gastric emptying and reducing glucagon release after mealtime.

## Definitions

“Amylin” is a hormone produced by the beta cells in the pancreas that is secreted at the same time as insulin. Its role is to regulate blood sugar and promote satiety (feeling of fullness) through slowing gastric emptying and suppressing glucagon release after mealtime.

“Blood Glucose” is the primary sugar found in the bloodstream, serving as the body's main energy source. Chronic high blood glucose levels can lead to complications from blood vessel damage.

“Glucagon” is a hormone produced by the pancreas which increases blood glucose by stimulating the liver to release stored glucose into the blood stream. It is a protective hormone against hypoglycemia (low blood sugar), and counteracts the effects of insulin.

“Hemoglobin A1c (HbA1c)” is a blood test that measures average blood glucose levels over the past 2 to 3 months. It is also referred to as the A1C or glycosylated hemoglobin test. Various factors, such as age, ethnicity, certain conditions, and pregnancy, can affect A1C results.

“Hyperglycemia” is the medical term for high blood glucose. It can occur due to inadequate fasting (fasting hyperglycemia) or post-meal (postprandial hyperglycemia).

“Hypoglycemia” is a condition characterized by abnormally low blood glucose, typically less than 70 mg/dL. Symptoms include hunger, nervousness, dizziness, confusion, and in severe cases,

unconsciousness. Immediate treatment involves consuming carbohydrate-rich foods or using injectable glucagon for severe cases.

"Insulin" is a hormone produced by the beta cells in the pancreas. It facilitates the entry of glucose into cells for energy production. Insufficient insulin leads to a high blood glucose level, a condition known as diabetes. Oral and injectable medications can help increase insulin production, enhance the body's sensitivity to insulin, and decrease blood sugar levels.

"[s]" indicates state mandates may apply.

"Type 1 Diabetes" is an autoimmune condition where the pancreas's beta cells are unable to produce sufficient insulin, leading to elevated blood glucose levels. Patients with Type 1 diabetes often require daily insulin injections to regulate their blood glucose.

"Type 2 Diabetes" is a metabolic disorder characterized by insufficient insulin production or insulin resistance in the body cells. It is more common than Type 1 and often managed through lifestyle changes, non-insulin medications, and, if necessary, insulin injections.

## Medical Necessity Criteria for Initial Clinical Review

### Initial Indication-Specific Criteria

#### Type 1 and Type 2 Diabetes Mellitus

The Plan considers SymlinPen (Pramlintide) medically necessary when BOTH the following criteria are met:

1. The member has a diagnosis of type 1 diabetes mellitus or type 2 diabetes mellitus; **AND**
2. The member has failed to achieve desired glucose control despite receiving optimal insulin therapy, including mealtime insulin.<sup>[s]</sup>

If the above prior authorization criteria are met, SymlinPen (Pramlintide) will be approved for up to 24 months.<sup>[s]</sup>

*Continued Care*

**Medical Necessity Criteria for Subsequent Clinical Review**

Subsequent Indication-Specific Criteria

**Type 1 and Type 2 Diabetes Mellitus**

The Plan considers SymlinPen (Pramlintide) medically necessary when ONE (1) of the following criteria are met:

1. A reduction in Hemoglobin A1c (HbA1c) since initiation of therapy, documented within the past 6 months; *or*
2. Maintenance of target HbA1c levels (e.g., HbA1c less than 7% or as determined by the treating provider based on member-specific goals); *or*
3. Improvement in fasting plasma glucose levels since initiation of therapy; *or*
4. Demonstrated improvement in other clinically relevant metrics, such as postprandial glucose levels or reduction in hypoglycemic episodes, as documented by the treating provider.

If the above reauthorization criteria are met, the requested product will be authorized for up to 24 months. [§]

**Experimental or Investigational / Not Medically Necessary**

SymlinPen (Pramlintide) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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#### Clinical Guideline Revision / History Information

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