RXADVANCE
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Clinical Policy Title:	pramlintide
Policy Number:	RxA.474
Drug(s) Applied:	Symlin®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Pramlintide (Symlin®) is an amylin analog. It is indicated 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pramlintide (Symlin®)	Type 1 or 2 diabetes	1 injection subcutaneous prior to each major meal (≥ 250 kcal or containing ≥ 30 g of carbohydrate) • Type 1 diabetes: start at 15 mcg • Type 2 diabetes: start at 60 mcg	Type 1: 60 mcg/injection Type 2: 120 mcg/injection

Dosage Forms

- Disposable 1.5 mL multidose pen-injector: 15 mcg, 30 mcg, 45 mcg, 60 mcg
- Disposable 2.7 mL multidose pen-injector: 60 mcg, 120 mcg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Diabetes Mellitus (must meet all)**:**

1. Diagnosis of type 1 or type 2 diabetes mellitus;
2. Prescribed by or in consultation with an endocrinologist;
3. Age 18 years of age or older;
4. Failure of three (3) or more daily mealtime insulin (e.g., Apidra®, Humalog®, Humulin® N, Humulin®R, Novolog®) injections, each used for at least three (3) months or more, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one of the following (a or b):
   a. For type 1 diabetes: 60 mcg prior to each major meal
   b. For type 2 diabetes: 120 mcg prior to each major meal

Approval duration:
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy

A. Diabetes Mellitus (must meet all)**:**

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by reduction in HbA1c at end of initial authorization period;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. For type 1 diabetes: 60 mcg prior to each major meal;
   b. For type 2 diabetes: 120 mcg prior to each major meal.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HbA1C: Hemoglobin A1c
SC: Subcutaneous/subcutaneously
U: Unit

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Apidra® (insulin glulisine)	Individualize dosage	Individualize dosage
Humalog® (insulin lispro)	0.5 to 1 U/kg SC daily	Individualize dosage
Humulin® R (regular insulin human)	0.5 to 1 U/kg SC daily	Individualize dosage
Humulin® N (NPH human isophane)	0.5 to 1 U/kg SC daily	Individualize dosage
Novolog® (insulin aspart)	Individualize dosage	Individualize dosage

Therapeutic alternatives are listed as Brand name®(generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Prior serious hypersensitivity reaction to pramlintide or its ingredients
  - Hypoglycemia unawareness
  - Confirmed gastroparesis

- Boxed warning(s):
  - Severe hypoglycemia

APPENDIX D: General Information

- Most common adverse reactions (incidence 5% or higher incidence than placebo): nausea, vomiting, anorexia and headache
- Store unopened pramlintide acetate injection in the refrigerator, between 36°F to 46°F (2°C to 8°C), until ready to use it.
- After a pramlintide acetate injection has been opened, it can be refrigerated or kept at room temperature between 36°F to 86°F (2°C to 30°C) for up to 30 days. Any pramlintide acetate injection in use should be thrown away after 30 days, even if still has pramlintide acetate injection in it.

References

1. Symlin Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019. Available at: www.symlin.com. Accessed October 13, 2020.
2. American Diabetes Association. Standards of medical care in diabetes—2018. Diabetes Care. 2018; 41(suppl 1): S1-S159. Accessed October 13, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/01/2020	03/06/2020
Policy was reviewed 1. Policy formatting updated. 2. Line of business policy applies was updated to All lines of business. 3. Criteria for approval updated (removal insulin pump criteria). 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. Approval length for commercial line of business updated to 6 months. 6. HIM approval duration removed. 7. Appendix B was updated. 8. Appendix D added and updated with adverse reactions and storage information. 9. References were reviewed and updated.	10/13/2020	12/07/2020