



# SmartPA Criteria Proposal

| Drug/Drug Class:           | Amylin Analogs PDL Edit  |  |  |
|----------------------------|--|--|--|
| First Implementation Date: | October 7, 2010  |  |  |
| Proposed Date:             | September 15, 2022   |  |  |
| Prepared For:              | MO HealthNet   |  |  |
| Prepared By:               | MO HealthNet/Conduent  |  |  |
| Criteria Status:           | <ul><li>☑ Existing Criteria</li><li>☐ Revision of Existing Criteria</li><li>☐ New Criteria</li></ul> |  |  |

#### **Executive Summary**

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Amylin is a naturally occurring neuroendocrine hormone synthesized by pancreatic beta cells that contribute to glucose control during the post-prandial period. Amylin is deficient in those with type 1 diabetes and relatively deficient in those with type 2 diabetes. Amylin is collocated with insulin in secretory granules and cosecreted with insulin by pancreatic beta cells in response to food intake. Amylin affects the rate of postprandial glucose appearance by slowing gastric emptying, regulates postprandial glucagon, and reduces food intake caused by centrally mediated modulation of appetite. In addition, amylin suppresses glucagon secretion, which leads to suppression of endogenous glucose output from the liver. SymlinPen® (pramlintide) is a synthetic analog of human amylin indicated as adjunctive treatment for type 1 or type 2 diabetic participants who use mealtime insulin therapy and have failed to achieve optimal glucose control. It is a stable, soluble, non-aggregating, and equipotent amylin analog that is administered subcutaneously with a meal. This medication acts like amylin and controls glucose levels without resultant weight gain. It also regulates postprandial glucose levels by slowing gastric emptying, promoting satiety, and suppressing the abnormal postprandial rise of glucagon in participants with diabetes. Pramlintide also has been shown to not cause hypoglycemia. The most common adverse effect is mild to moderate nausea that generally goes away after 4 weeks of therapy, and the risk of which may be reduced by slower dose titrations.

Total program savings for the PDL classes will be regularly reviewed.

| Program-Specific  | Preferred Agents  | Non-Preferred Agents  |
|-------------------|---|---|
| Information:      | SymlinPen®  | • N/A   |
| Type of Criteria: | <ul><li>☐ Increased risk of ADE</li><li>☐ Appropriate Indications</li></ul> | <ul><li>☑ Preferred Drug List</li><li>☐ Clinical Edit</li></ul> |
| Data Sources:     | ☐ Only Administrative Databases   | □ Databases + Prescriber-Supplied                               |

# **Setting & Population**

- Drug class for review: Amylin Analogs
- Age range: All appropriate MO HealthNet participants

## **Approval Criteria**

• Documented insulin therapy regimen

### **Denial Criteria**

• Therapy will be denied if all approval criteria are not met

## **Required Documentation**

| Laboratory Results: | Progress Notes | s: |
|---------------------|----------------|----|
| MedWatch Form:      | Other:         |    |

## **Disposition of Edit**

Denial: Exception Code "0681" (Step Therapy Edit)

Rule Type: CE

## **Default Approval Period**

1 year

#### References

- Evidence-Based Medicine Analysis: "Antidiabetic Mimetics", UMKC-DIC; March 2018.
- American Diabetes Association (ADA). Standards of Medical Care in Diabetes 2022. Diabetes Care. 2022;45(suppl 1): S1-S264.
- Dungan, K., (2019). Amylin analogs for the treatment of diabetes mellitus. In J.E. Mulder (Ed.), UpToDate.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.