

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | Amylin Analogs PDL Edit |
| First Implementation Date: | October 7, 2010 |
| Proposed Date: | June 17, 2021 |
| Prepared For: | MO HealthNet |
| Prepared By: | MO HealthNet/Conduent |
| Criteria Status: | <input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria |

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. Symlin® (pramlintide) is a synthetic analog of human amylin used 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 causing 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 this may be reduced by titrating up the dose more slowly.

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

| Program-Specific Information: | Preferred Agents | Non-Preferred Agents |
|-------------------------------|---|----------------------|
| | <ul style="list-style-type: none"> Symlin Pen® | |

- Type of Criteria:**
- | | |
|--|---|
| <input type="checkbox"/> Increased risk of ADE | <input checked="" type="checkbox"/> Preferred Drug List |
| <input type="checkbox"/> Appropriate Indications | <input type="checkbox"/> Clinical Edit |
- Data Sources:**
- | | |
|--|---|
| <input type="checkbox"/> Only Administrative Databases | <input checked="" type="checkbox"/> 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:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception Code "0681" (Step Therapy Edit)
Rule Type: CE

Default Approval Period

1 year

References

1. Drug Effectiveness Review Project – “Drug Class Review on Newer Diabetes Medications and Combinations”, Center for Evidence-Based Policy, Oregon Health & Science University; February 2011; Update Report July 2016.
2. Evidence-Based Medicine Analysis: “Antidiabetic Mimetics”, UMKC-DIC; March 2018.
3. American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. *Diabetes Care*. 2021;44(suppl 1): S1-S232.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
6. Symlin [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; December 2019.
7. Dungan, K., (2019). Amylin analogs for the treatment of diabetes mellitus. In J.E. Mulder (Ed.), *UpToDate*.