SmartPA Criteria Proposal

Drug/Drug Class:	Insulin, Non-Analogs PDL Edit
First Implementation Date:	October 19, 2005
Proposed Date:	September 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒ Existing Criteria ☐ Revision of Existing Criteria ☐ New Criteria

Executive Summary

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

Why Issue Selected: Type 1 diabetes mellitus occurs when the body's immune system destroys the insulin-secreting beta cells of the pancreas. The management of type 1 diabetes has changed dramatically over the past 30 years. New insulin strategies have improved the ability to maintain near-normal glycemia. All non-analog insulins have demonstrated the ability to lower hemoglobin $A1_C$. Efficacy and safety profiles are similar among these agents. Humulin® N, Novolin® N and ReliOn® Novolin® N are intermediate-acting neutral protamine Hagedorn (NPH) insulins while Humulin® R, Novolin® R, ReliOn® Novolin® R and Humulin® R U-500 are short-acting regular insulins. Humulin R U-500 may be used in patients requiring > 200 units of insulin per day. Factors such as onset, peak, and duration of action can influence the ability of an insulin regimen to help control glucose levels. Patient factors, including individual variations in insulin absorption, levels of exercise and types of meals consumed, also influence the effectiveness of insulin regimens.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Humulin® N Vial	• Humulin® N KwikPen®
• Humulin® R Vial	• Novolin® N FlexPen®
• Humulin® R U-500 KwikPen®/Vial	• Novolin® R FlexPen®
• Novolin® N Vial	• ReliOn® Novolin® N FlexPen®/Vial
• Novolin® R Vial	• ReliOn® Novolin® R FlexPen®/Vial

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List** ☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Insulin, Non-Analogs
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For Humulin R U-500: documented compliance on prior insulin therapy (90/120 days) **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Insulin Products", UMKC-DIC; February 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Insulins - Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2022. *Diabetes Care.* 2022;45(suppl 1): S1-S264.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.