SmartPA Criteria Proposal

Drug/Drug Class:	Insulin, Long Acting PDL Edit
First Implementation Date:	July 3, 2008
Proposed Date:	July 18, 2023
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. Long-acting insulins are for once or twice daily subcutaneous administration helping to restore the ability of the body to properly utilize carbohydrates, fats, and proteins. All long-acting insulins have demonstrated the ability to lower hemoglobin A1c. In newer clinical trials, the longer acting basal analogs have shown positive outcomes in lower hypoglycemic rates. 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
• Lantus® SoloStar®/Vial • Levemir® FlexTouch®/Vial	• Basaglar® KwikPen, **Tempo™ Pen** • **Insulin Degludec Pen/Vial** • Insulin Glargine Solostar U100 & 100 Unit/mL Vial • Insulin Glargine-YFGN (gen Semglee®) • **Rezvoglar™** • Semglee® (YFGN) • Toujeo® SoloStar®/Max SoloStar® • Tresiba® FlexTouch®/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, Long Acting
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- 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 and Fiscal Analysis: “Therapeutic Class Review: ENDROCRINE AND METABOLIC AGENTS: Insulins, Long Acting”, Gainwell Technologies; Last updated April 13, 2023.
- Evidence-Based Medicine Analysis: “Endocrine and Metabolic Agents: Insulins, Long Acting”, UMKC-DIC; February 2023.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.