SmartPA Criteria Proposal

Drug/Drug Class:	Sulfonylurea Agents, Second Generation PDL Edit
First Implementation Date:	May 11, 2005
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 2 diabetes mellitus is a significant health problem associated with excessive morbidity and mortality. As the prevalence of this metabolic disorder is rapidly increasing and as older treatments fail to stabilize the disease in many participants, prevention and control are considered key objectives. Type 2 diabetes mellitus is characterized by insulin resistance, impaired insulin secretion and overproduction of hepatic glucose. Evidence suggests that insulin resistance is the predominant factor preceding the onset of hyperglycemia. Sulfonylureas increase insulin secretion at stimulatory levels lower than that required for glucose, suggesting that they enhance beta-cell response rather than change beta-cell sensitivity to glucose. Current guidelines suggest other agents are more beneficial and have lower incidences of adverse events. Glimepiride has demonstrated a lower incidence of hypoglycemia and weight gain compared to other sulfonylureas in clinical trials. Glyburide is contraindicated in older adults due to its longer duration of effects.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Glimepiride • Glipizide • Glipizide ER • Glyburide • Glyburide Micronized	• Amaryl® • Glucotrol® • Glucotrol XL® • Glynase® PresTab®

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: Sulfonylurea Agents, Second Generation

- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
  - Documented trial period of 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
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
AMARYL 1 MG	GLIMEPIRIDE	2 tablets per day
AMARYL 2 MG	GLIMEPIRIDE	2 tablets per day
AMARYL 4 MG	GLIMEPIRIDE	2 tablets per day
GLUCOTROL XL 10 MG	GLIPIZIDE	2 tablets per day
GLUCOTROL XL 2.5 MG	GLIPIZIDE	1 tablet per day
GLUCOTROL XL 5 MG	GLIPIZIDE	1 tablet per day
GLYNASE PRESTAB 1.5 MG	GLYBURIDE, MICRONIZED	1 tablet per day
GLYNASE PRESTAB 3 MG	GLYBURIDE, MICRONIZED	1 tablet per day
GLYNASE PRESTAB 6 MG	GLYBURIDE, MICRONIZED	2 tablets per day

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: ENDOCRINE AND METABOLIC AGENTS: Antihyperglycemic, Oral Sulfonylurea, 2nd Generation”, Gainwell Technologies; Last updated April 20, 2023.
- Evidence-Based Medicine Analysis: “2nd Generation Sulfonylureas”, UMKC-DIC; March 2023.
- American Diabetes Association (ADA). Standards of Care in Diabetes – 2023. *Diabetes Care.* 2022;46(suppl 1): S1-S291.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.