SmartPA Criteria Proposal

Drug/Drug Class:	Sulfonylureas, 2nd Generation PDL Edit
First Implementation Date:	May 11, 2005
Proposed Date:	June 18, 2020
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 XL® • Glucotrol® • 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: Sulfonylureas, 2nd 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 no approval criteria are met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
AMARYL 1 MG	GLIMEPIRIDE	1 tablet per day
AMARYL 2 MG	GLIMEPIRIDE	1 tablet 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

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. American Diabetes Association (ADA). Standards of Medical Care in Diabetes-2020. *Diabetes Care.* 2020;43(suppl 1): S1-S212.
5. Evidence-Based Medicine and Fiscal Analysis: "Antihyperglycemic, Oral Sulfonylurea, Second Generation – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; May 2020.
6. Drug Effectiveness Review Project – Drug Class Review on "Oral Hypoglycemics". Center for Evidence-Based Policy, Oregon Health & Science University; April 2005/May 2014 (Updated Scan).
7. Evidence-Based Medicine Analysis: "2nd Generation Sulfonylureas", UMKC-DIC; April 2020.
8. 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatric Soc.* 2019;67(4):674-694.
9. Amaryl [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; 2019.
10. Glucotrol [package insert]. New York, NY: Pfizer; 2018.
11. Glucotrol XL [package insert]. New York, NY: Pfizer; 2018.
12. Glynase PresTab [package insert]. New York, NY: Pfizer & Co; 2017.