

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Sulfonylurea Agents, Second Generation PDL Edit
<b>First Implementation Date:</b>	May 11, 2005
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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:** 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
	<ul style="list-style-type: none"> <li>• Glimepiride</li> <li>• Glipizide</li> <li>• Glipizide ER</li> <li>• Glyburide</li> <li>• Glyburide Micronized</li> </ul>	<ul style="list-style-type: none"> <li>• Amaryl<sup>®</sup></li> <li>• Glucotrol<sup>®</sup></li> <li>• Glucotrol XL<sup>®</sup></li> <li>• Glynase<sup>®</sup> PresTab<sup>®</sup></li> </ul>

**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	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:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

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

## Default Approval Period

1 year

## References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. Diabetes Care. 2021;44(suppl 1): S1-S232.

SmartPA PDL Proposal Form

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4. Evidence-Based Medicine and Fiscal Analysis: “Antihyperglycemic, Oral Sulfonylurea, Second Generation – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; May 2020.
5. 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).
6. Evidence-Based Medicine Analysis: “2<sup>nd</sup> Generation Sulfonylureas”, UMKC-DIC; April 2020.
7. 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.
8. Amaryl [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; December 2018.
9. Glucotrol [package insert]. New York, NY: Pfizer; December 2020.
10. Glucotrol XL [package insert]. New York, NY: Pfizer; August 2018.
11. Glynase PresTab [package insert]. New York, NY: Pfizer & Co; October 2017.

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