



Drug/Drug Class: Sulfonylureas, 2nd Generation PDL Edit First Implementation Date: May 11, 2005 Revised Date: October 1, 2020 Prepared For: MO HealthNet Prepared By: MO HealthNet/Conduent Criteria Status: ⊠Existing Criteria □ Revision of Existing Criteria □ New 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 | Amaryl® | | |
| Glipizide | Glucotrol XL® | | |
| Glipizide ER | Glucotrol® | | |
| Glyburide | Glynase® PresTab® | | |
| Glyburide Micronized | | | |

| 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 all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

| 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 |

| | GLYNASE PRESTA | B 3 MG | GLYBURIDE, MICRONIA | ZED | 1 tablet per day | 1 | |
|---|------------------------------------|--------|---------------------------|-----|-------------------|---|--|
| | GLYNASE PRESTA | B 6 MG | GLYBURIDE, MICRONIZ | ZED | 2 tablets per day | ı | |
| • | | | | | | | |
| Requ | Required Documentation | | | | | | |
| | poratory Results: adWatch Form: | | Progress Notes: Other: | | | | |
| Disposition of Edit | | | | | | | |
| Denial: Exception Code "0160" (Preferred Drug List) Rule Type: PDL | | | | | | | |
| Default Annual Devices | | | | | | | |

Default Approval Period

1 year

References

- 1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
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- 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.
- 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.
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