

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | Thiazolidinediones & Combination Agents PDL Edit |
| First Implementation Date: | January 8, 2009 |
| Proposed Date: | June 18, 2020 |
| Prepared For: | MO HealthNet |
| Prepared By: | MO HealthNet/Conduent |
| Criteria Status: | <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. Thiazolidinediones (TZDs) improve glycemic control by improving insulin sensitivity in muscle and adipose tissue and inhibit hepatic gluconeogenesis. They depend on the presence of insulin for their mechanism of action. TZDs have known significant adverse events, such as new onset of congestive heart failure, edema, and hepatic failure. TZDs should not be used by individuals with NYHA Class III or IV heart failure as they can cause fluid retention. The 2020 American Diabetes Association Standards of Medical Care in Diabetes recognizes TZDs as possible second line agents in addition to metformin in participants who do not have cardiovascular disease or chronic kidney disease. These agents are also available in oral combination agents that include ActoplusMet® (pioglitazone/metformin) and Duetact® (pioglitazone/glimepiride).

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"> • Pioglitazone | <ul style="list-style-type: none"> • ActosplusMet® • ActosplusMet® XR • Actos® • Avandia® • Duetact® • Pioglitazone/Glimepiride • Pioglitazone/Metformin |

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Thiazolidinediones & Combination Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 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
- Documented diagnosis of heart failure in the past 2 years
- Inferred heart failure defined as treatment on 3 or more agents in the inferred therapy groups (i.e. digoxin, loop diuretics, ACE inhibitors, ARBs, beta blockers) in the past 2 years
- For Avandia: concurrent use of insulin **OR** nitrates in the past 30 days
- Claim exceeds maximum dosing limitation for the following:

| | | |
|--|--|-------------------|
| | | |
| | | 3 tablets per day |
| | | 3 tablets per day |
| | | 2 tablets per day |
| | | 1 tablet per day |
| | | 1 tablet per day |
| | | 1 tablet per day |
| | | 1 tablet per day |
| | | 2 tablets per day |
| | | 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. Evidence-Based Medicine and Fiscal Analysis: "Oral Antihyperglycemics: Thiazolidinediones (TZDs) and Combination Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; May 2020.
5. Drug Effectiveness Review Project – Drug Class Review on Thiazolidinediones. Center for Evidence-Based Policy, Oregon Health & Science University; May 2006/Update September 2009.
6. Evidence-Based Medicine Analysis: "Thiazolidinediones", UMKC-DIC; February 2020.
7. American Diabetes Association (2017). Standards of Medical Care in Diabetes-2017. *Diabetes Care*, 40 (Supplement 1): S1-S142.
8. Avandia [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2019.
9. Actos [package insert]. Deerfield, IL: Takeda Pharmaceuticals America Inc; 2017.
10. American Diabetes Association (ADA). Standards of Medical Care in Diabetes-2020. *Diabetes Care*. 2020;43(suppl 1): S1-S212.

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SmartPA PDL Proposal Form

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