SmartPA Criteria Proposal

Drug/Drug Class:	Thiazolidinediones & Combination Agents PDL Edit
First Implementation Date:	January 8, 2009
Proposed Date:	June 17, 2021
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. 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 2021 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
• Pioglitazone	• ActoplusMet® • 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

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- Documented diagonsis of heart failure
- For Avandia: concurrent use of insulin **OR** nitrates in the past 30 days
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
ACTOPLUS MET 15MG/500MG	PIOGLITAZONE/METFORMIN	3 tablets per day
ACTOPLUS MET 15MG/850MG	PIOGLITAZONE/METFORMIN	3 tablets per day
ACTOS 15 MG	PIOGLITAZONE	1 tablet per day
ACTOS 30 MG	PIOGLITAZONE	1 tablet per day
ACTOS 45 MG	PIOGLITAZONE	1 tablet per day
AVANDIA 2 MG	ROSIGLITAZONE	2 tablets per day
AVANDIA 4 MG	ROSIGLITAZONE	2 tablets per day
DUETACT 30-4 MG TABLET	**PIOGLITAZONE/GLIMEPIRIDE**	**1 tablet per day**
DUETACT 30-2 MG TABLET	**PIOGLITAZONE/GLIMEPIRIDE**	**1 tablet 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. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021Clinical Drug Information, LLC.
3. Evidence-Based Medicine and Fiscal Analysis: “Oral Antihyperglycemics: Thiazolidinediones (TZDs) and Combination Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.

4. Drug Effectiveness Review Project – Drug Class Review on Thiazolidinediones. Center for Evidence-Based Policy, Oregon Health & Science University; May 2006/Update September 2009.
5. Evidence-Based Medicine Analysis: "Thiazolidinediones", UMKC-DIC; March 2021.
6. American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. Diabetes Care. 2021;44(suppl 1): S1-S232.
7. Avandia [package insert]. Research Triangle Park, NC: GlaxoSmithKline; November 2020.
8. Actos [package insert]. Deerfield, IL: Takeda Pharmaceuticals America Inc; June 2020.
9. American Diabetes Association (ADA). Standards of Medical Care in Diabetes-2020. *Diabetes Care.* 2020;43(suppl 1): S1-S212.