Drug/Drug Class: Thiazolidinediones & Combination Agents PDL Edit
First Implementation Date: January 8, 2009
Revised Date: October 1, 2020
Prepared For: MO HealthNet
Prepared By: MO HealthNet/Conduent
Criteria Status: ☒ Revision of Existing 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:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pioglitazone</td>
<td>ActosplusMet®</td>
</tr>
<tr>
<td></td>
<td>Actos®</td>
</tr>
<tr>
<td></td>
<td>Avandia®</td>
</tr>
<tr>
<td></td>
<td>Duetact®</td>
</tr>
<tr>
<td></td>
<td>Pioglitazone/Glimepiride</td>
</tr>
<tr>
<td></td>
<td>Pioglitazone/Metformin</td>
</tr>
</tbody>
</table>

Type of Criteria: ☒ Preferred Drug List

Data Sources: ☒ Only Administrative Databases

Setting & Population

Other company trademarks are also acknowledged.
• 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
  o Documented trial period of preferred agents OR
  o 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
  • 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:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dosing Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTOPLUS MET 15MG/500MG</td>
<td>PIOGLITAZONE/METFORMIN</td>
<td>3 tablets per day</td>
</tr>
<tr>
<td>ACTOPLUS MET 15MG/850MG</td>
<td>PIOGLITAZONE/METFORMIN</td>
<td>3 tablets per day</td>
</tr>
<tr>
<td>ACTOS 15 MG</td>
<td>PIOGLITAZONE</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>ACTOS 30 MG</td>
<td>PIOGLITAZONE</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>ACTOS 45 MG</td>
<td>PIOGLITAZONE</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>AVANDIA 2 MG</td>
<td>ROSIGLITAZONE</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>AVANDIA 4 MG</td>
<td>ROSIGLITAZONE</td>
<td>2 tablets per day</td>
</tr>
</tbody>
</table>

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

2. USPDI, Micromedex; 2020.  
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.  