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. Metformin monotherapy and combination therapy are generally well tolerated and improve glycemic control and lipid concentrations in patients with non-insulin-dependent diabetes mellitus, whose diabetes is poorly controlled with diet or sulfonylurea therapy alone. Metformin decreases hepatic glucose output by inhibiting gluconeogenesis by reducing glucose substrate availability through its antilipolytic effect which decreases serum free fatty acid concentrations. It also increases insulin-mediated glucose use in peripheral tissues such as in the muscle and liver, typically after meals. In addition, metformin also activates the AMP-activated protein kinase (AMPK) enzyme in hepatocytes which contributes to decreases serum lipid concentrations. The most common adverse effects are gastrointestinal related, metallic taste, vitamin B12 deficiency, and lactic acidosis. It is recommended to take these agents with meals to reduce gastrointestinal adverse effects.

Total program savings for the PDL classes will be regularly reviewed.
**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: Biguanides & Combination Agents
- Age range: All appropriate MO HealthNet participants

**Approval Criteria**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Glumetza and Fortamet: adequate therapeutic trial on generic Glucophage and/or Glucophage XR (90/120 days) **OR**
- For Riomet ER: Clinical Consultant Review

**Denial Criteria**
- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- 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>FORTAMET ER 1,000 MG</td>
<td>METFORMIN ER</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>FORTAMET ER 500 MG</td>
<td>METFORMIN ER</td>
<td>5 tablets per day</td>
</tr>
<tr>
<td>GLUCOPHAGE XR 500 MG</td>
<td>METFORMIN ER</td>
<td>4 tablets per day</td>
</tr>
<tr>
<td>GLUCOPHAGE XR 750 MG</td>
<td>METFORMIN ER</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>GLUCOVANCE 1.25 MG/250 MG</td>
<td>GLYBURIDE/METFORMIN</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>GLUCOVANCE 2.5 MG/500 MG</td>
<td>GLYBURIDE/METFORMIN</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>GLUCOVANCE 5 MG/500 MG</td>
<td>GLYBURIDE/METFORMIN</td>
<td>4 tablets per day</td>
</tr>
<tr>
<td>GLUMETZA ER 1,000 MG</td>
<td>METFORMIN ER</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>GLUMETZA ER 500 MG</td>
<td>METFORMIN ER</td>
<td>4 tablets per day</td>
</tr>
<tr>
<td>METAGLIP 2.5 MG/250 MG</td>
<td>GLIPIZIDE/METFORMIN</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>METAGLIP 2.5 MG/500 MG</td>
<td>GLIPIZIDE/METFORMIN</td>
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</table>

**Required Documentation**

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
</table>

**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.