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. Since 2015, the American Diabetes Association (ADA) Standards of Medical Care in Diabetes were updated to include the sodium-glucose co-transporter 2 (SGLT2) inhibitors in the management algorithm for type 2 diabetes mellitus. Although SGLT2 inhibitors are approved for monotherapy, metformin is still the preferred initial treatment, with the SGLT2 inhibitors added to the regimen if weight loss is also a goal. The most common side effects associated with these agents are urinary tract infections and female genital mycotic infections. Jardiance® (empagliflozin) was the first SGLT2 inhibitor to demonstrate benefit in reducing cardiovascular disease risk in persons with type 2 diabetes mellitus. It is believed that the beneficial effect of improving cardiovascular outcomes may be a class effect of the SGLT2 inhibitors. ADA guidelines favor Invokana® (canagliflozin), Jardiance® (empagliflozin), and Farxiga® (dapagliflozin) due to these agents’ lower risks for heart failure and progression of chronic kidney disease. Dapagliflozin was recently approved by the FDA for use to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class I to IV).

Total program savings for the PDL classes will be regularly reviewed.

<table>
<thead>
<tr>
<th>Program-Specific Information:</th>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Farxiga®</td>
<td>Invokamet®</td>
</tr>
<tr>
<td></td>
<td>Invokana®</td>
<td>Invokamet® XR</td>
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<td></td>
<td>Jardiance®</td>
<td>Segluromet™</td>
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<td>Synjardy®</td>
<td>Steglatro™</td>
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<tr>
<td></td>
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<td>Synjardy® XR</td>
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<td></td>
<td></td>
<td>Trijardy® XR</td>
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<td></td>
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<td>Xigduo® XR</td>
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</tbody>
</table>
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: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors & Combination Agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- For first claim only:
  - Documented diagnosis of Diabetes Mellitus Type 2 AND
  - Documented trial of metformin in the past year OR
- For Farxiga only: Documented diagnosis of Heart Failure
- 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

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- For first claim only:
  - Documented diagnosis of severe renal impairment or end stage renal disease OR
  - Documented diagnosis of severe hepatic impairment
- 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>FARXIGA 10 MG</td>
<td>DAPAGLIFLOZIN</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>FARXIGA 5 MG</td>
<td>DAPAGLIFLOZIN</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>INVOKANA 100 MG</td>
<td>CANAGLIFLOZIN</td>
<td>2 tablets per day</td>
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<tr>
<td>INVOKANA 300 MG</td>
<td>CANAGLIFLOZIN</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>JARDIANCE 10 MG</td>
<td>EMPAGLIFLOZIN</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>JARDIANCE 25 MG</td>
<td>EMPAGLIFLOZIN</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>STEGLATRO 15 MG</td>
<td>ERTUGLIFLOZIN</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>STEGLATRO 5 MG</td>
<td>ERTUGLIFLOZIN</td>
<td>2 tablets per day</td>
</tr>
</tbody>
</table>

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

2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
11. Drug Effectiveness Review Project – Drug Class Review Newer Diabetes Medications and Combinations - Center for Evidence-Based Policy, Oregon Health & Science University; February 2011, Updated July 2016.