Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Antiandrogenic agents inhibit the action of androgens on tumor growth in prostatic tissue. Most drugs in this class work by interfering with androgen receptor activation, androgen receptor signaling, or androgen biosynthesis. Most are indicated for use in metastatic prostate cancer, aside from additional indications of nonmetastatic castration resistant prostate cancer in Nubeqâ® (darolutamide) and Xtandi® (enzalutamide). All second generation antiandrogenic agents should be given with gonadotropin-releasing hormone analog, aside from Erleada®, which should be given concurrently with androgen deprivation therapy. Dosage adjustment are required for Xtandi in patients taking concomitant strong CYP2C8 inhibitors or concomitant strong CYP3A4 inducers. Due to the mechanism of action for this class of drugs, patients may experience similar symptoms as those with androgen deficiency, including gynecomastia, and may increase risk for heart disease.

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>Abiraterone</td>
<td>Erleada®</td>
</tr>
<tr>
<td>Xtandi® Caps</td>
<td>Nubeqâ®</td>
</tr>
<tr>
<td>Zytiga® 500 mg</td>
<td>Xtandi® Tabs</td>
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<tr>
<td></td>
<td>Yonsa®</td>
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<td></td>
<td>Zytiga® 250 mg</td>
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</tbody>
</table>

Type of Criteria: ☒ Preferred Drug List

Data Sources: ☒ Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Antiandrogenic Agents
- Age range: All appropriate MO HealthNet participants
Approval Criteria

- Claim is for a preferred agent OR
- Documented compliance on current therapy regimen OR
- Failure to achieve desired therapeutic outcomes with trial of Xandi capsules AND
- For Yonsa: failure to achieve desired therapeutic outcomes with trial of preferred abiraterone
- For Zytiga 250 mg: Clinical Consultant Review required for approval

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

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

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: “Non-Steroidal Antiandrogens/Androgen Biosynthesis Inhibitors”, UMKC-DIC; August 2021.
- USPDI, Micromedex; 2021.