Executive Summary

**Purpose:** Ensure appropriate utilization and control of Oxandrin® (oxandrolone)

**Why Issue Selected:** Oxandrin® is an oral tablet formulation of the anabolic steroid oxandrolone. It was FDA approved in 1964 and became a Schedule III controlled substance in 1991. Oxandrin is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma or in patients who fail to gain or maintain normal weight without definite pathophysiologic reasons. It is also indicated to offset the protein catabolism associated with prolonged administration of corticosteroids and for the relief of the bone pain frequently accompanying osteoporosis. Due to the specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Oxandrin.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Date Range FFS 7-1-2020 to 6-30-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXANDROLONE 2.5 MG TABLET</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>$17,126.19</td>
</tr>
<tr>
<td></td>
<td>$300.45</td>
</tr>
<tr>
<td>OXANDROLONE 10 MG TABLET</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>$1,789.55</td>
</tr>
<tr>
<td></td>
<td>$447.38</td>
</tr>
</tbody>
</table>

**Type of Criteria:** ☒ Appropriate Indications  ☒ Clinical Edit

**Data Sources:** ☒ Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Oxandrin® (oxandrolone)
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Diagnosis of bone pain associated with osteoporosis OR
- Diagnosis of protein catabolism associated with chronic corticosteroids OR
- To promote weight gain:
  - Documented history of extensive surgery, chronic infection, or severe trauma OR
Documented failure to gain or maintain at least 90% of ideal body weight due to underlying disease state (ex. COPD or AIDS) OR
• Approval based on clinical consultant review

Denial Criteria

• Therapy will be denied if all approval criteria are not met
• Participant is currently pregnant

Required Documentation

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

MedWatch Form: [ ]
Other: [ ]

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

30 days

References