Executive Summary

Purpose: Ensure appropriate usage 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.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Date Range FFS 01-01-2019 to 06-30-2019</th>
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<tbody>
<tr>
<td>Drug</td>
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<tr>
<td>Oxandrolone 2.5mg tab</td>
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<tr>
<td>Oxandrolone 10mg tab</td>
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</tbody>
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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: 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 no approval criteria are met
• Participant is currently pregnant

Required Documentation

Laboratory Results:  
MedWatch Form:  
Progress Notes:  
Other:  X

Disposition of Edit

Denial: Exception code “682” (Clinical Edit)
Rule Type: CE

Default Approval Period

30 days

References