Drug/Drug Class: Megestrol Acetate Clinical Edit
First Implementation Date: August 12, 2010
Revised Date: July 21, 2022
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of megestrol acetate

Why Issue Selected: Megestrol is a synthetic oral progestin with slight glucocorticoid and mineralocorticoid activity. Megestrol acetate tablets are indicated for palliative treatment of advanced carcinoma of the breast or endometrium. The suspension is indicated for the treatment of anorexia, cachexia, or unexplained significant weight loss in patients with acquired immunodeficiency syndrome (AIDS). Due to the possible adverse events and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of megestrol acetate.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 1-1-2021 to 12-31-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEGESTROL 40 MG/ML SUSP</td>
<td>506  $18,468.42  $36.49</td>
</tr>
<tr>
<td>MEGESTROL 625 MG/5 ML SUSP</td>
<td>7  $1,429.97  $204.28</td>
</tr>
<tr>
<td>MEGESTROL 20 MG TABLET</td>
<td>136  $2490.98  $18.31</td>
</tr>
<tr>
<td>MEGESTROL 40 MG TABLET</td>
<td>514  $12,567.87  $24.45</td>
</tr>
</tbody>
</table>

Type of Criteria: ☒ Appropriate Indications

Data Sources: ☒ Only Administrative Databases

Setting & Population

- Drug class for review: Megestrol acetate
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Participant is compliant with current therapy (90 out of 120 days) OR
- Claim is for megestrol 40 mg/ml suspension or tablets OR
- Claim is for megestrol 625 mg/5 ml suspension:
Documented diagnosis of malignant neoplasm of the breast, uterus, or ovaries OR
Documented diagnosis of HIV/AIDS with cachexia AND
Documented therapeutic trial of megestrol 40 mg/ml suspension or tablets in the past 2 years

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant
- Claim exceeds maximum daily dosage limitations:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dose Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEGESTROL 40 MG/ML SUSP</td>
<td>MEGESTROL ACETATE</td>
<td>800 mg</td>
</tr>
<tr>
<td>MEGESTROL 625 MG/5 ML SUSP</td>
<td>MEGESTROL ACETATE</td>
<td>625 mg</td>
</tr>
<tr>
<td>MEGESTROL 20 MG TABLET</td>
<td>MEGESTROL ACETATE</td>
<td>800 mg</td>
</tr>
<tr>
<td>MEGESTROL 40 MG TABLET</td>
<td>MEGESTROL ACETATE</td>
<td>800 mg</td>
</tr>
</tbody>
</table>

Required Documentation

- Laboratory Results:
- Progress Notes:
- MedWatch Form: [ ]
- Other: [X]

Disposition of Edit

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

Default Approval Period

3 months

References