Clinical Edit Criteria Proposal

Drug/Drug Class: Megestrol Acetate Clinical Edit
Date: August 12, 2010
Prepared for: MO HealthNet
Prepared by: MO HealthNet

☐ New Criteria  ☒ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate and prudent use of megestrol acetate within the MO HealthNet Pharmacy program.

Why was this Issue Selected: Megestrol is a synthetic female hormone belonging to the progesterone family. Megestrol is indicated for palliative treatment of advanced carcinoma of the breast or endometrium. It is also used to stimulate appetite and promote weight gain in patients with muscle wasting due to cancer or in patients with acquired immunodeficiency syndrome (AIDS).

Program-specific information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Megestrol Acetate (oral)</td>
<td>2,229</td>
<td>$110,013</td>
</tr>
<tr>
<td>Megace ES</td>
<td>32</td>
<td>$20,409</td>
</tr>
<tr>
<td>Megace 40mg/ml</td>
<td>1</td>
<td>$48.90</td>
</tr>
</tbody>
</table>

$130,472 total

Setting & Population: Patients 18 years of age and older

Type of Criteria: ☐ Increased risk of ADE  ☐ Non-Preferred Agent
☒ Appropriate Utilization  ☐ Other:

Data Sources: ☒ Only administrative databases  ☐ Databases + Prescriber-supplied
Setting & Population

- Drug/drug class for review: Megestrol Acetate
- Age range: All patients 18 years of age and older
- Gender: males and females

Approval Criteria

- Appropriate diagnosis – or inferred
  - Malignant neoplasm – breast { ICD-9 codes 174.0 – 174.9 }
  - Malignant neoplasm – uterus { ICD-9 codes 182 – 182.0 }
  - HIV/AIDS plus
    - Cachexia

<table>
<thead>
<tr>
<th>ICD-9 Diagnosis Code Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition</td>
</tr>
<tr>
<td>Breast Cancer</td>
</tr>
<tr>
<td>Malignant Neoplasm, uterus</td>
</tr>
<tr>
<td>HIV</td>
</tr>
<tr>
<td>Cachexia</td>
</tr>
</tbody>
</table>

Denial Criteria

- Megace ES or Megace 40mg/ml as first line therapy (generic preferred)
- Pregnancy
- Doses exceeding
  - 800mg/day for Megestrol Acetate
  - 625mg/day for Megace ES
- Lack of compliance on first-line therapy regimen
- Lack of appropriate diagnoses
  - Utilization for cachexia in the absence of HIV/AIDS diagnosis

Required Documentation

- Laboratory results: 
- MedWatch form: 
- Progress notes: 

Disposition of Edit

- **Denial:** Edit 682 “Clinical Edit”

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2009.