# SmartPA Criteria Proposal

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|---|---|
| **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:** | ☐Existing Criteria<br>☒Revision of Existing Criteria<br>☐New 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:**

| Date Range FFS 1-1-2021 to 12-31-2021 | | | |
|---|---|---|---|
| **Drug** | **Claims** | **Spend** | **Avg Spend per Claim** |
| MEGESTROL 40 MG/ML SUSP | 506 | $18,468.42 | $36.49 |
| MEGESTROL 625 MG/5 ML SUSP | 7 | $1,429.97 | $204.28 |
| MEGESTROL 20 MG TABLET | 136 | $2490.98 | $18.31 |
| MEGESTROL 40 MG TABLET | 514 | $12,567.87 | $24.45 |

**Type of Criteria:**
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

**Data Sources:**
☒ **Only Administrative Databases**
☐ **Databases + Prescriber-Supplied**

## 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:

| Drug Description | Generic Equivalent | Max Dose Per Day |
|---|---|---|
| MEGESTROL 40 MG/ML SUSP | MEGESTROL ACETATE | 800 mg |
| MEGESTROL 625 MG/5 ML SUSP | MEGESTROL ACETATE | 625 mg |
| MEGESTROL 20 MG TABLET | MEGESTROL ACETATE | 800 mg |
| MEGESTROL 40 MG TABLET | MEGESTROL ACETATE | 800 mg |

## 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


- Facts & Comparisons. Megestrol Oral. Accessed February 2, 2022.
- Clinical Pharmacology. Megestrol. Accessed February 2, 2022.