SmartPA Criteria Proposal

Drug/Drug Class:	Megestrol Acetate Clinical Edit
First Implementation Date:	August 12, 2010
Proposed Date:	April 18, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 1-1-2022 to 12-31-2022			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
MEGESTROL 40 MG/ML SUSP	984	$24,945.79	$25.45
MEGESTROL 625 MG/5 ML SUSP	38	$251.43	$6.62
MEGESTROL 20 MG TABLET	260	$3,080.28	$11.85
MEGESTROL 40 MG TABLET	900	$14,689.13	$16.32

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 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 January 19, 2023.