SmartPA Criteria Proposal

Drug/Drug Class:	Megestrol Acetate Clinical Edit
First Implementation Date:	August 12, 2010
Proposed Date:	March 19, 2020
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 with loss in patients with acquired immunodeficiency syndrome (AIDS).

Program-Specific Information:

Date Range FFS 1-1-2019 to 12-31-2019			
Drug	**Claims**	**Spend**	**Cost per day (usual dosing)**
MEGACE ES 625 MG/5 ML SUSP	40	$12,930.46	$11.55 NADAC
MEGESTROL ACET 40 MG/ML SUSP	371	$15,239.65	$1.80 NADAC
MEGESTROL 20 MG TABLET	75	$1,725.15	$0.96 MAC
MEGESTROL 40 MG TABLET	239	$7,284.55	$0.84 MAC

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

- Claim is within maximum daily dosage limitations (see Appendix A) **AND**
- Participant is compliant with current therapy (90 out of 120 days) **OR**
- Documented diagnosis of malignant neoplasm of the breast, uterus, or ovaries or HIV/AIDS with cachexia in the past 2 years **AND**

- Claim for 625mg/5ml suspension: documented therapeutic trial of 40mg/ml suspension or tablets in the past 2 years

Denial Criteria

- Therapy will be denied if no approval crieria are met
- Participant is currently pregnant

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

1 year

Appendix A

Drug Description	Generic Equivalent	Max Dose Per Day
MEGACE 40 MG/ML ORAL SUSP	MEGESTROL ACETATE	800 mg
MEGACE ES 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

References

- Facts & Comparisons. Megestrol Acetate Oral. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5548495?searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DMegestrol%2520Acetate%26t%3Dname%26va%3Dmeges. Accessed December 30, 2019.
- Clinical Pharmacology. Megestrol. https://www.clinicalkey.com/pharmacology/monograph/370?n=Megestrol. Accessed December 30, 2019.
- Megace ES (megestrol acetate) oral suspension [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; December 2018.