Clinical Policy: Megestrol Acetate 125 mg/mL Oral Suspension (Megace ES)

Reference Number: PA.CP.PMN.179
Effective Date: 10/2018
Last Review Date: 10/2023

Revision Log

Description
Megestrol acetate 125 mg/mL oral suspension (Megace® ES) is a progestin.

FDA Approved Indication(s)
Megace ES is indicated for the treatment of anorexia, cachexia, or an unexplained significant weight loss in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS).

Limitation(s) of use:
- Therapy with megestrol acetate for weight loss should only be instituted after treatable causes of weight loss are sought and addressed. These treatable causes include possible malignancies, systemic infections, and gastrointestinal disorders affecting absorption, endocrine disease, renal disease, or psychiatric diseases.
- Megestrol acetate is not intended for prophylactic use to avoid weight loss.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Megace ES is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Megace ES (must meet all)**:**
1. Member must use megestrol acetate 40 mg/mL oral suspension, unless contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed 625 mg (5 mL) per day.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. Request for Megace ES (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, new dose does not exceed 625 mg (5 mL) per day.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AIDS: acquired immunodeficiency syndrome
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
megestrol acetate 40 mg/mL	400 to 800 mg QD	800 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity, known or suspected pregnancy
- Boxed Warning(s): none reported

Appendix D: General Information
- Megace ES is not equivalent to other formulations on a mg-per-mg basis (e.g., megestrol acetate 40 mg/mL).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Anorexia, cachexia, or unexplained significant weight loss associated with AIDS	625 mg PO QD (5 mL or one teaspoon daily)	625 mg (5 mL) per day

VI. Product Availability
Oral suspension: 625 mg/5 mL (125 mg/mL)

VII. References
1. Megace ES Prescribing Information. Malvern, PA: Endo Pharmaceutical, Inc.; December 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021778s024lbl.pdf. July 6, 2023.
2. Ruiz Garcia V, López-Briz E, Carbonell Sanchis R, Gonzalvez Perales JL, Bort-Marti S. Megestrol acetate for treatment of anorexia-cachexia syndrome. *Cochrane Database Syst Rev*. 2013;2013(3):CD004310. Published 2013 Mar 28.
3. Nemcheck PM, Polsky B, and Gottlieb MS. Treatment guidelines for HIV-associated wasting. Subspeciality clinicals: infectious diseases. April 2000;75(4):p386-394.

4. Clinical Pharmacology [database online] Tampa, FL: Gold Standard, Inc.; 2020. Available at http://www.clinicalpharmacology-ip.com. Accessed July 11, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: References reviewed and updated.	07/2020	
4Q 2021 annual review: no significant changes; changed megestrol 40 mg/mL requirement to "Member must use…" language; references reviewed and updated.	10/2021	
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022	
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023	