

Clinical Policy: Megestrol Acetate (Megace ES)

Reference Number: CP.PMN.179

Effective Date: 12.01.18

Last Review Date: 11.20

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Megestrol acetate 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 health plans affiliated with Centene Corporation[®] 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. Age \geq 18 years;
2. Medical justification supports inability to use megestrol acetate 40 mg/mL oral suspension (e.g., contraindication to excipients);
3. 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 Centene benefit or member has previously met initial approval criteria;
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 PO 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/day)	625 mg/day (5 mL/day)

VI. Product Availability

Oral suspension: 625 mg/5 mL in 150 mL

VII. References

1. Megace ES Prescribing Information. Spring Valley, NY: Par Pharmaceutical Companies, Inc.; December 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021778s024lbl.pdf. Accessed July 3, 2020.
2. Ruiz Garcia V, López-Briz E, Carbonell Sanchis R, Gonzalez 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. Clinical Pharmacology [database online] Tampa, FL: Gold Standard, Inc.; 2020. Available at <http://www.clinicalpharmacology-ip.com>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy HIM.PA.128; Medicaid line of business added; no significant changes; references reviewed and updated.	08.14.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.25.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.03.20	11.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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