Clinical Policy: Megestrol Acetate

Reference Number: CP.PMN.179
Effective Date: 12.01.18
Last Review Date: 11.25
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 is a progestin.

FDA Approved Indication(s)

Megestrol acetate 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.

This policy is applicable to megestrol acetate 125 mg/mL oral solution. It is the policy of health plans affiliated with Centene Corporation® that megestrol acetate is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Megestrol Acetate 125 mg/mL Oral Solution (must meet all)**:**

1. Age ≥ 18 years;
2. Member must use megestrol acetate 40 mg/mL oral suspension, unless contraindicated or clinically significant adverse effects are experienced;*
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
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 Megestrol Acetate 125 mg/mL Oral Solution (must meet all)**:**

1. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

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
- Megestrol acetate 125 mg/mL oral solution 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. Megestrol Acetate Oral Suspension Prescribing Information. Paramus, NJ: TWi Pharmaceutical, Inc.; March 2023. Available at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=2dc921d5-e423-4379-a345-151e87d13651&type=pdf. Accessed July 9, 2025.
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]. Philadelphia, PA: Elsevier. Updated periodically. Available at http://www.clinicalkey.com/pharmacology. Accessed August 13, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes; changed megestrol 40 mg/mL requirement to "Member must use…" language; references reviewed and updated.	07.14.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to continued therapy section.	08.16.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	07.06.23	11.23
4Q 2024 annual review: removed brand Megace ES from policy due to product discontinuation; clarified that this policy is applicable to generic megestrol acetate 125 mg/mL oral solution; references reviewed and updated.	07.16.24	11.24
4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	07.09.25	11.25

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.