Clinical Policy: Megestrol Acetate 125 mg/mL Oral Suspension (Megace ES)
Reference Number: CP.PMN.179
Effective Date: 12.01.18
Last Review Date: 11.18
Line of Business: HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

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 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 ≥ 18 years;
      2. Member is contraindicated or has experienced clinically significant adverse effects to the excipients in megestrol acetate 40 mg/mL oral suspension;
      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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>megestrol acetate</td>
<td>400 to 800 mg QD</td>
<td>800 mg/day</td>
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   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 (125 mg/mL) is not substitutable with other strengths (e.g., Megace 40 mg/mL).

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anorexia, cachexia, or unexplained significant weight loss associated with AIDS</td>
<td>625 mg PO QD (5 mL/day)</td>
<td>625 mg/day (5 mL/day)</td>
</tr>
</tbody>
</table>

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

VII. References
CLINICAL POLICY
Megesterol Acetate 125 mg/mL Oral Suspension

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created: adapted from previously approved policy</td>
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<td></td>
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<tr>
<td>HIM.PA.128; Medicaid line of business added; no significant changes; references reviewed and</td>
<td>08.14.18</td>
<td>11.18</td>
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<tr>
<td>updated.</td>
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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.
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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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