Clinical Policy: Omega-3-Acid Ethyl Esters (Lovaza)
Reference Number: CP.PMN.52
Effective Date: 08.01.12
Last Review Date: 02.19
Line of Business: Medicaid

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

Description
Omega-3-acid ethyl esters (Lovaza®) is a combination of ethyl esters of omega 3 fatty acids, principally eicosapentaenoic acid and docosahexaenoic acid.

FDA Approved Indication(s)
Lovaza is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Limitation(s) of use:
- The effect of Lovaza on the risk for pancreatitis has not been determined.
- The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

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 Lovaza is medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Hypertriglyceridemia (must meet all):
   1. Diagnosis of hypertriglyceridemia;
   2. Age ≥ 18 years;
   3. Fasting triglycerides ≥ 500 mg/dL (lab must be dated within 90 days);
   4. Failure of a ≥ 3 consecutive month trial of fibrate therapy in the last 6 months at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   5. If request is for brand Lovaza, medical justification supports inability to use generic omega-3-acid ethyl esters (e.g., contraindication to excipients);
   6. Dose does not exceed 4 g (4 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications
   1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.
II. Continued Therapy

A. Hypertriglyceridemia (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. Member is responding positively to therapy;
   3. If request is for a dose increase, new dose does not exceed 4 g (4 capsules) per day.
   
   **Approval duration: 12 months**

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   
   **Approval duration: Duration of request or 12 months (whichever is less); or**
   
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

   Appendix A: Abbreviation/Acronym Key
   
   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 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>fenofibrate (TriCor®)</td>
<td>48-145 mg PO QD</td>
<td>145 mg/day</td>
</tr>
<tr>
<td>gemfibrozil (Lopid®)</td>
<td>600 mg PO BID</td>
<td>1,200 mg/day</td>
</tr>
</tbody>
</table>

   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): patients with known hypersensitivity (e.g., anaphylactic reaction) to Lovaza or any of its components
   - Boxed warning(s): none reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertriglyceridemia</td>
<td>4 g PO QD or 2 g PO BID</td>
<td>4 g/day</td>
</tr>
</tbody>
</table>
VI. Product Availability
Capsule: 1 g

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>References updated</td>
<td>08.01.14</td>
<td>08.14</td>
</tr>
<tr>
<td>Converted to new template</td>
<td>08.01.15</td>
<td>08.15</td>
</tr>
<tr>
<td>The following was added to criteria: lab result must be within the last 30 days; use of fibrate for ≥ 3 consecutive months in the last 6 months; quantity limit of 4 capsules per day was added. Initial approval period was extended to 6 months instead of 3 months to time for provider to evaluate patient’s response. Renewal criteria requiring 10% decrease in baseline triglyceride was removed to allow provider to make the decision to discontinue/continue therapy.</td>
<td>05.01.16</td>
<td>08.16</td>
</tr>
<tr>
<td>Updated template and references. Added option for intolerance/contraindication in lieu of failure of fibrate therapy and requirement for previous fulfilment of Centene coverage criteria for continued approval. Modified specific max dosing criteria to generalized statement. Added workflow document.</td>
<td>11.01.16</td>
<td>11.16</td>
</tr>
<tr>
<td>Initial approval period was updated for labs in 90 days instead of 30 days.</td>
<td>03.01.17</td>
<td>08.17</td>
</tr>
<tr>
<td>Removed age requirement as age is not an absolute contraindication. References updated.</td>
<td>11.16.17</td>
<td>02.18</td>
</tr>
<tr>
<td>1Q18 annual review: - Age added - No significant changes - References reviewed and updated.</td>
<td>11.20.18</td>
<td>02.19</td>
</tr>
<tr>
<td>1Q 2019 annual review: added redirection to generic Lovaza; references reviewed and updated.</td>
<td>11.16.17</td>
<td>02.18</td>
</tr>
</tbody>
</table>
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.

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