LAETRILE AND RELATED SUBSTANCES (NCD 30.7)

Guideline Number: MPG187.04  Approval Date: October 10, 2018

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POLICY SUMMARY

Overview
Laetrile has been used primarily in the treatment or control of cancer. Although the terms "Laetrile," "laetrile," "Sarcinase," "vitamin B-17," "amygdalin," and "nitriloside" have been used interchangeably, the chemical identity of the substances to which these terms refer has varied.

Guidelines
The FDA has determined that neither Laetrile nor any other drug called by the various terms mentioned above, nor any other product which might be characterized as a "nitriloside" is generally recognized (by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs) to be safe and effective for any therapeutic use. Use of this drug cannot be considered to be reasonable and necessary within the meaning of §1862(a)(1) of the Act and program payment may not be made for its use or any services furnished in connection with its administration.

Payment may not be made for laetrile (or other drug noted above) when it is used during the course of an otherwise covered hospital stay. A hospital stay only for the purpose of having laetrile (or any other drug called by the terms mentioned above) administered is not covered.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J3570</td>
<td>Laetrile, amygdalin, vitamin B-17 (Not Covered by Medicare)</td>
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PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used.
to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 30.7 Laetrile and Related Substances

CMS Benefit Policy Manual
Chapter 1: § 30.2 Approval by Pharmacy and Drug Therapeutics Committee
Chapter 15: § 50 Drugs and Biologicals

CMS Claims Processing Manual
Chapter 17: § 80.1 Oral Cancer Drugs, § 90.2 Drugs, Biologicals, and Radiopharmaceuticals

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>10/10/2018</td>
<td>• Annual review</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.