

Laetrile and Related Substances (NCD 30.7)

Policy Number	30.7	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	09/24/2014
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IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided.

UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation.

Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable

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ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Overview

Laetrile (and the other drugs called by the various terms mentioned below) have been used primarily in the treatment or control of cancer. Although the terms "Laetrile," "laetrile," "amygdalin," "Sarcarinase," "vitamin B-17," and "nitriloside" have been used interchangeably, the chemical identity of the substances to which these terms refer has varied.

Reimbursement 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. Therefore, 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.

A hospital stay only for the purpose of having laetrile (or any other drug called by the terms mentioned above) administered is not covered. Also, program 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.

CPT/HCPCS Codes

Code	Description
J3570	Laetrile, amygdalin, vitamin B-17 (Not Covered by Medicare)

References Included (but not limited to):

CMS NCD

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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

CMS Transmittals

Transmittal 127, Change Request 1005, Dated 10/06/2000

UnitedHealthcare Medicare Advantage Coverage Summaries

Medications/Drugs (Outpatient/Part B)

History

Date	Revisions
09/24/2014	Annual review; No changes
09/11/2014	Removed liability references
08/14/2013	Administrative updates
08/22/2012	Administrative updates