

Local Coverage Determination (LCD): Lab: Coenzyme Q10 (CoQ10) (L37066)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID

Original Effective Date

L37066

For services performed on or after 10/02/2017

LCD Title

Lab: Coenzyme Q10 (CoQ10)

Revision Effective Date

For services performed on or after 01/01/2020

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL37066

Retirement Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Notice Period Start Date

08/17/2017

Notice Period End Date

10/01/2017

Current Dental Terminology © 2019 American Dental Association. All rights reserved.

Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are

considered to be reasonable and necessary.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for serum or other body fluid testing for levels of Coenzyme Q10 (CoQ10 or Q10), also known as ubiquinone, ubidecarenone, coenzyme Q, for all diseases. Q10 supplementation is purported to:

- Prolong life and prevent age-related functional declines,
- Inhibit the development and/or progression of atherosclerosis,
- Have value as an adjunct to conventional medical therapy in the treatment of congestive heart failure, conventional angina therapy, and cancer,
- Is protective against myocardial damage during ischemia-reperfusion during cardiac surgery,
- Is beneficial in the treatment of hypertension, cardiovascular disease and diabetes,
- Plays a role in neurodegenerative diseases such as Parkinson's disease, Huntington's disease, Friedreich's ataxia,
- Enhance athletic performance, and
- Enhance fertility.

However, scientific indications for Q10 supplementation, except as anecdotally reported for rare mitochondrial encephalomyopathies, are poor and/or controversial, as are indications for Q10 testing by any methodology.

Q10 is a highly lipophilic molecule with a chemical structure similar to vitamin K. Its most prominent role is to facilitate the production of adenosine triphosphate (ATP) in the mitochondria by participating in redox reactions within the electron transport chain. Two major factors lead to deficiency of Q10 in humans: reduced biosynthesis and increased use by the body. As many as 12 genes control biosynthesis, although Q10 levels may be controlled by other genetic defects not directly related to Q10 biosynthesis.

Summary of Evidence

Heart disease

Q10 shares a biosynthetic pathway with cholesterol. An intermediary precursor of Q10 is inhibited by some beta blockers, anti-hypertensive medications and statins, but the role of statins in deficiencies is controversial.¹

Some chronic disease conditions (cancer, heart disease, etc.) are also thought to reduce the biosynthesis of and increase the demand for CoQ10 in the body, but there are no definite data to support these claims.²

A 2014 Cochrane Collaboration meta-analysis found "no convincing evidence to support or refute" the use of CoQ10 for the treatment of heart failure.³ Evidence with respect to preventing heart disease in those who are otherwise healthy is also poor.⁴

Statin myopathy

Q10 has been routinely used to treat muscle breakdown associated as a side effect of use of statin medications. However, evidence from randomized controlled trials does not appear to support the idea that CoQ10 is an effective treatment for statin myopathy.⁵

Cancer

No large well-designed clinical trials of CoQ10 in cancer treatment have been done.⁶ The National Cancer Institute identified issues with the few, small studies that have been done stating, "the way the studies were done and the amount of information reported made it unclear if benefits were caused by the CoQ10 or by something else."⁶ The American Cancer Society has concluded, "CoQ10 may reduce the effectiveness of chemo and radiation therapy, so most oncologists would recommend avoiding it during cancer treatment."

Neuromuscular and Neurologic Diseases

Available evidence suggests that "CoQ10 is likely ineffective in moderately improving" the chorea associated with Huntington's disease.⁷

Migraine headache

Supplementation of CoQ10 has been found to have a beneficial effect on the condition of some sufferers of migraine. An explanation for this is the theory that migraines are a mitochondrial disorder,⁸ and that mitochondrial dysfunction can be improved with CoQ10.⁹ The Canadian Headache Society guideline for migraine prophylaxis recommends, based on low-quality evidence, that 300 mg of CoQ10 be offered as a choice for prophylaxis.¹⁰

Dental disease

A review study has shown that there is no clinical benefit to the use of CoQ10 in the treatment of periodontal disease.¹¹ Most of the studies suggesting otherwise were outdated, focused on in-vitro tests, too few test subjects and/or erroneous statistical methodology and trial set-up, or were sponsored by a manufacturer of the product.

Mitochondrial encephalomyopathies

This group of genetic disorders results from abnormalities in the function of the mitochondrial transport chain. Tissue Q10 deficiencies have been found in a very small subpopulation of individuals with mitochondrial encephalomyopathies.¹² In these rare individuals, Q10 supplementation has resulted in clinical improvement.¹³

Male infertility

Q10 can improve some measurements regarding sperm quality. However, there is no evidence that Q10 increases pregnancy rates or live births.¹⁴

Analysis of Evidence

(Rationale for Determination)

Level of Evidence

Quality - 2C

Strength - Weak

Wright - Weak

Based on the results of multiple articles representing multiple conditions, the scientific evidence to support coverage of Q10 for any purpose is controversial and/or limited for all diseases. Randomized controlled studies are recommended to demonstrate clinical utility. Consequently, testing for Q10 is not a Medicare benefit.

General Information

Associated Information

No comments were received for this draft LCD for comment period ending 4/10/2017.

Sources of Information

See Bibliography

Bibliography

1. Trevisson E, Dimauro S, Navas P, Salviati L. Coenzyme Q deficiency in muscle. *Curr. Opin. Neurol.* ; 2011;24 (5): 449–56.
2. Sharma A, Fonarow GC, Butler J, et al. Coenzyme Q10 and Heart Failure. *Circulation: Heart Failure* 2016; 9:e002639.
3. Madmani ME, Yusuf Solaiman A, Tamr Agha K, et al. Coenzyme Q10 for heart failure. *Heart Group. Cochrane Database of Systematic Reviews*. John Wiley & Sons 2014;(6): Art. no. CD008684.
4. Mortensen SA, Rosenfeldt F, Kumar A, et al. The effect of coenzyme q10 on morbidity and mortality in chronic heart failure. *Heart Failure. American College of Cardiology Foundation* 2014;(6): 641–9.
5. Banach M, Serban C, Sahebkar A, et al. Effects of coenzyme Q10 on statin-induced myopathy: a meta-analysis of randomized controlled trials. *Mayo Clin Proc (Systematic Review and Meta-Analysis)*. Lipid and Blood Pressure Meta-analysis Collaboration Group.2015; 90 (1): 24–34.
6. White, J. National Cancer Institute. PDQ[®] Coenzyme Q10. NCI, National Institutes of Health, U.S. Dept. of Health and Human Services. May 14, 2014.
7. Armstrong, MJ; Miyasaki, JM. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology*. 2012;79 (6): 597–603.
8. Markley HG. "CoEnzyme Q10 and riboflavin: the mitochondrial connection". *Headache (Review)*. 2012;52 Suppl 2: 81–7.
9. Yorns WR, Hardison HH. Mitochondrial dysfunction in migraine. *Semin Pediatr Neurol*. 2013;20 (3): 188–93.
10. Pringsheim T, Davenport W, Mackie G, et al. "Canadian Headache Society guideline for migraine prophylaxis". *Can J Neurol Sci*. 2012;39 (2 Suppl 2): S1–59.
11. Watts TLP. Coenzyme Q10 and periodontal treatment: is there any beneficial effect? *British Dental Journal*. Department of Periodontology and Preventive Dentistry, UMDS, Guy's Hospital London. 1995;178 (6): 209–13.

12. Rotig A, Appelkvist EL, Geromel V, et al. Quinone-responsive multiple respiratory-chain dysfunction due to widespread coenzyme Q10 deficiency. *Lancet*. 2000;356(9227):391-395

13. Munnich A, Rotig A, Cormier-Daire V, Rustin P. Clinical presentation of respiratory chain deficiency. In: Scriver CR, Beaudet AL, Sly WS, Valle D, eds. *The metabolic and molecular bases of inherited disease*. 8th ed. Volume 2. New York: McGraw-Hill; 2001;2261-74.

14. Lafuente R, González-Comadrán M, Solà I, et al. Coenzyme Q10 and male infertility: a meta-analysis. *Journal of assisted reproduction and genetics*. 2013;30 (9): 1147–56.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R5	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
01/01/2020	R4	<p>Additional information for revision #3: As required by CR 10901, all billing and coding information has been moved to the companion article; this article is linked to the LCD.</p> <p>This revision adds to revision #3 to remove CMS National Coverage Policy references that do not address coverage from the LCD. These have been added to the related Billing and Coding article.</p> <p>01/01/2020: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Creation of Uniform LCDs With Other MAC Jurisdiction
10/01/2019	R3	<p>10/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage</p>	<ul style="list-style-type: none"> Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p> <p>This LCD was converted to the "no-codes" format.</p>	
04/30/2018	R2	<p>02/25/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p> <p>Update to add "Lab" to the title and delete reference #7 in the Summary of Evidence and Bibliography.</p>	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction
04/30/2018	R1	<p>Removed reference #9 in the Bibliography section because it was withdrawn. Also removed the content referencing #9. Corrected bibliography numbering and references 10-15 throughout the policy.</p>	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A55769 - Billing and Coding: Lab: Coenzyme Q10 (CoQ10)

LCD(s)

DL37066

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/28/2020 with effective dates 01/01/2020 - N/A

Updated on 12/19/2019 with effective dates 01/01/2020 - N/A

Updated on 10/04/2019 with effective dates 10/01/2019 - 12/31/2019

Updated on 02/25/2019 with effective dates 04/30/2018 - 09/30/2019

Updated on 04/19/2018 with effective dates 04/30/2018 - N/A

Keywords

- Coenzyme
- CoQ10
- Q10
- ubiquinone
- ubidecarenone
- coenzyme Q
- Lab