

Local Coverage Determination (LCD): Lab: Coenzyme Q10 (CoQ10) (L37068)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

LCD ID
L37068

Original Effective Date

For services performed on or after 10/02/2017

LCD Title

Revision Effective Date

Lab: Coenzyme Q10 (CoQ10)

For services performed on or after 02/25/2021

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL37068

Retirement Date

N/A

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Notice Period Start Date

08/17/2017

Notice Period End Date

10/01/2017

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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 for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

42 CFR §410.32(a) indicates that diagnostic tests may be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements).

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
- 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; Q10 levels may also 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, antihypertensive 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 is 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 setup, 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

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
02/25/2021	R6	<p>Under CMS National Coverage Policy updated description for regulation Title XVIII of the Social Security Act, §1862(a)(1)(A) to read "allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis and treatment of illness or injury to improve the functioning of a malformed body member" and updated description for regulation 42 CFR §410.32(a) to read "indicates that diagnostic tests may be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements". under Bibliography changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout 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"> Provider Education/Guidance
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.)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
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>01/01/2019: 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>	<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 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>	<ul style="list-style-type: none"> • Revisions Due To Code Removal
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)

A55770 - Billing and Coding: Lab: Coenzyme Q10 (CoQ10)

LCD(s)

DL37068

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 02/15/2021 with effective dates 02/25/2021 - N/A

Updated on 01/29/2020 with effective dates 01/01/2020 - 02/24/2021

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

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

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