

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

Please Note: This view is an approximation of the CMS MCD LCD Detail page.

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 L37066 | Original Effective Date For services performed on or after 10/02/2017 |
| LCD Title Lab: Coenzyme Q10 (CoQ10) | Revision Effective Date For services performed on or after 04/30/2018 |
| Proposed LCD in Comment Period N/A | Revision Ending Date N/A |
| Source Proposed LCD <u>DL37066 - Coenzyme Q10 (CoQ10)</u> | Retirement Date N/A |
| | 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.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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

CMS On-Line Manual, Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical

Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, *Medicare Claims Processing Manual*, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (*Medicare Claims Processing Manual*), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes."

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, ubiquinone, 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.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

| CODE | DESCRIPTION |
|-------|----------------|
| XX000 | Not Applicable |

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

| CODE | DESCRIPTION |
|-------|----------------|
| XX000 | Not Applicable |

ICD-10 Codes that DO NOT Support Medical Necessity

Additional ICD-10 Information

N/A

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

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Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|--|--|
| 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 - Coenzyme Q10 (Q10) Coding and Billing Guideline

LCD(s)

DL37066 - Coenzyme Q10 (CoQ10)

Related National Coverage Documents

N/A

Public Version(s)

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

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

Updated on 08/03/2017 with effective dates 10/02/2017 - N/A

Keywords

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