

Pharmacy Medical Necessity Guidelines: Coenzyme Q10

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: Commercial Products <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization Tufts Health Public Plans Products <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		Fax Numbers: RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Mitochondrial disease is a diverse group of genetic disorders affecting cellular energy production. The consequences of these disorders may involve any combination of a variety of body systems including the brain and muscles (causing poor stamina, seizures, altered muscle tone, muscle weakness, strokes); autonomic nervous system (temperature dysregulation, heart rate abnormalities, blood pressure dysregulation, poor heat tolerance, increased sweating, skin pallor and blotching); eyes (vision loss); hearing deficit; endocrine disease (diabetes mellitus, hypothyroidism, hypoparathyroidism, adrenal insufficiency); heart (cardiomyopathy); liver (dysfunction, cirrhosis); kidneys (renal tubular acidosis); metabolic issues (lactic acidosis). Symptoms become especially severe during ordinary infections, often with ordinary exercise, with significant psychological stress, and sometimes with excessive heat or humidity. The natural course of these disorders is variable in symptom intensity and is extremely variable even within the same genetic defect. Coenzyme Q10 is one of the factors involved in energy production within the cells. Supplementation with oral Coenzyme Q10 is believed to improve the intracellular levels of this factor and improve energy production by the cell. An improvement in energy production by the cell will diminish the consequences of the genetic defect.

COVERAGE GUIDELINES

The plan may authorize coverage of Coenzyme Q10 for Members with mitochondrial disease, when the following criteria are met:

1. Documented diagnosis of a mitochondrial disorder (enzyme analysis, and/or molecular DNA lesion, and/or characteristic pathology)

OR

- 2a. Inconclusive alternative diagnostic testing

AND

- 2b. Documentation of all of the following:

- Multiple system involvement, and
- Progression in clinical, radiologic, or biochemical markers of the disease, and
- Documentation of variable nature of the symptoms

OR

- 3a. Definitive diagnosis of Mitochondrial Enzymatic Disorder in a first degree relative

AND

- 3b. Documentation of at least two of the criteria in 2b

LIMITATIONS

None

CODES

None

1063093

REFERENCES

1. AACE Nutrition Guidelines Task Force "American Association of Clinical Endocrinologists Medical Guidelines for the Clinical Use of Dietary Supplements and Nutraceuticals." *Endocrine Practice* 2003 September/October; 9(5):417-70.
2. Cohen, BH "Mitochondrial Cytopathies: A Primer." June 2000, Cleveland Clinic Foundation.
3. DiMauro, S and Schon, EA, "Mitochondrial Respiratory-Chain Diseases." *New England Journal of Medicine*. 2003 June 26;348(26): 2656-68.
4. Gold, DR and Cohen BH. Treatment of mitochondrial cytopathies. *Semin Neurol*. 2001 Sep;21(3):309-25.
5. Mancuso M, Angelini C, Bertini E, Nation-wide Italian Collaborative Network of Mitochondrial Diseases. Fatigue and exercise intolerance in mitochondrial diseases. Literature revision and experience of the Italian Network of mitochondrial diseases. *Neuromuscul Disord*. 2012 Dec;22 Suppl 3:S226-9. doi: 10.1016/j.nmd.2012.10.012.
6. Nicolson, GL. Mitochondrial dysfunction and chronic disease: treatment with natural supplements. *Altern Ther Health Med*. 2014 Winter;20 Suppl 1: 18-28.

APPROVAL HISTORY

October 12, 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 9, 2005: No changes
- July 11, 2006: No changes
- July 10, 2007: No changes
- May 13, 2008: No changes
- May 12, 2009: No changes
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- March 9, 2010: No changes
- March 8, 2011: No changes
- February 14, 2012: No changes
- February 12, 2013: No changes
- December 10, 2013: No changes
- December 9, 2014: No changes
- November 10, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- November 15, 2016: No changes
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- November 14, 2017: No changes
- November 13, 2018: No changes
- December 10, 2019: No changes
- November 10, 2020: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic. [Provider Services](#)