Mass General Brigham
Health Plan

Antioxidants
Effective 10/02/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Pedmark (sodium thiosulfate) is available under the medical benefit only.		

Overview

Coenzyme Q10 is a naturally occurring, lipid-soluble antioxidant used for cellular energy. Many of the therapeutic benefits of Coenzyme Q10 are attributed to its antioxidant properties and role in adenosine triphosphate (ATP) production. Coenzyme Q10 helps reduce oxidative stress and is essential for the proper transfer within the mitochondrial chain in order to produce ATP. For these reasons, Coenzyme Q10 serves as a potentially useful therapy in mitochondrial disease (MD). Coenzyme Q10, in combination with other vitamins, continues to be recommended as a core part of the mitochondrial disease regimen and is generally recommended for all patients.

Pedmark is a novel branded formulation of sodium thiosulfate (STS). Generic STS is FDA approved for the treatment of cyanide poisoning, but is regularly used off-label for calciphylaxis (particularly in dialysis patients) and extravasation management.

Drugs That Require PA
Coenzyme Q10† ≥ 22 years old
Coenzyme Q10 Combination products*
Pedmark (sodium thiosulfate) [MB]

*Coenzyme Q10 for members < 22 years old and vitamin E (oral) are available separately without prior authorization-please refer to the OTC list. In addition, coenzyme Q10 combinations with vitamin E are covered for members < 22 years old as long as there are no other ingredients included within the formulation.

† Please refer to the Pharmaceutical Compounding guideline if the request is a for a compound with coenzyme Q10 powder or ubiquinol powder.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

Coenzyme Q10 ≥ 22 years of age

1. Diagnosis of Mitochondrial disease (MD)*
2. **ONE** of the following
    a. Muscle biopsy (e.g., lab reports may be labeled as oxidation phosphorylation or electron chain reports or positive for MD as defined by a defect or decreased activity of any electron transport complex [Complexes I-V]-listed on the report)
    b. Pathogenic mtDNA abnormality (e.g., a positive result as defined by the presence of mutant mitochondrial DNA or any mention of point mutations associated with MD)

* Requests for members with siblings with MD: if a member has a sibling with MD, we can consider the member a positive carrier

Pedmark (sodium thiosulfate)

1. Diagnosis of localized, non-metastatic solid tumor
2. Prescriber is an oncologist
3. Member is ≥ one month and < 18 years of age
4. Member is receiving cisplatin with an infusion duration ≤ 6 hours
5. Appropriate dosing

Continuation of Therapy
Reauthorizations by prescriber will infer a positive response to therapy.

Limitations

1. Initial and reauthorization approvals will be granted for 12 months
2. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
3. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

References

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11. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Adolescent and Young Adult (AYA) Oncology. Version 3.2023. 2023 Jan 9 [cited 2023 Apr 24]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/aya.pdf.

Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL. Effective 4/1/23.
07/12/23 – Reviewed and updated for P&T. Renamed policy to Antioxidants (formerly named Coenzyme Q10). Pedmark added to policy requiring PA under MB. Brand preferred and mandatory generic language was added under Limitations. Effective 07/31/23
09/13/23 – Reviewed and updated for P&T. Coenzyme Q10 powder and ubiquinol powder will be removed from age restrictions and will be managed with cost allowance threshold and route of administration via the Pharmaceutical Compounding guideline. No clinical changes. Effective 10/2/23