

<u>Antioxidants</u> Pedmark (sodium thiosulfate) Effective 06/01/2025

Plan	 ☑ MassHealth UPPL □Commercial/Exchange 		Prior Authorization
Benefit	 Pharmacy Benefit Medical Benefit 	Program Type	Quantity Limit Step Therapy
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

Overview

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.

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:

- 1. Diagnosis of localized, non-metastatic solid tumor
- 2. Prescriber is an oncologist
- 3. Member is \geq one month and < 18 years of age
- 4. Member is receiving cisplatin with an infusion duration \leq 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.

References

1. Natural Medicines Comprehensive Database [database on the internet]. Stockton (CA): Natural Medicines; 2022 Mar 18 [cited 2022 Mar 24]. Available from: www.naturaldatabase.com

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

- Newman CB, Preiss D, Tobert JA, Jacobson TA, Page 2nd RL, Goldstein LB, et al. Statin Safety and Associated Adverse Events: A Scientific Statement From the American Heart Association. Arterioscler Thromb Vasc Biol. 2019 Feb;39(2):e38-e81. 9 Administered for the MassHealth Pharmacy Program
- Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun 25;73(24):3168-3209.
- 4. Pedmark [prescribing information]. Hoboken (NJ): Fennec Pharmaceuticals, Inc.; 2024 Oct.
- 5. Freyer DR, Brock PR, Chang KW, Dupuis LL, Epelman S, Knight K et al. Prevention of cisplatin-induced ototoxicity in children and adolescents with cancer: a clinical practice guideline. Lancet Child Adolesc Health. 2020 Feb;4(2):141-150.
- 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

05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Coenzyme Q10 agents were pharmacy benefit only and thus have been removed. Updated formatting & references accordingly. Effective 6/1/25