

**Generic Name:** Tiopronin**Therapeutic Class or Brand Name:** Thiola**Applicable Drugs (if Therapeutic Class):** N/A**Preferred:** Tiopronin tablets (generic)**Non-preferred:** Thiola, Thiola EC**Date of Origin:** 5/7/2015**Date Last Reviewed / Revised:** 11/9/2023

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation that Thiola is used for the prevention of cystine (kidney) stone formation in patients with severe homozygous cystinuria.
- II. Documentation that urinary cystine is greater than 500 mg/day.
- III. Documented resistance or contraindication to treatment with conservative measures of high fluid intake, alkali, and diet modification.
  - A. Minimum age requirement: 9 years old.
  - B. Minimum weight for pediatric patients is 20 kg.
- IV. Prescribed by or in consultation with a nephrologist or urologist.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

## EXCLUSION CRITERIA

- Patient has a prior history of developing agranulocytosis, aplastic anemia, or thrombocytopenia while on Thiola.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- The usual starting dose of Thiola is 800 mg/day for adults or 15 mg/kg/day for children. The dose should be based on the amount required to reduce urinary cystine concentration to below its solubility limit (generally < 250 mg/liter). The quantity is limited to a maximum of a 30 day supply per fill.

## APPROVAL LENGTH

- **Authorization:** 6 months

- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective. Must include documentation that the urinary cystine concentration is below its solubility limit (generally < 250 mg/liter) and that it is being measured at least every 6 months.

## APPENDIX

N/A

## REFERENCES

1. Pearle MS, et. al., Medical management of kidney stones: AUA guideline. J Urol. 2014 Aug;192(2):316-24. doi: 10.1016/j.juro.2014.05.006. Epub 2014 May 20.
2. Qaseem A, Dallas P, Forcica MA, Starkey M, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Dietary and pharmacologic management to prevent recurrent nephrolithiasis in adults: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014 Nov 4;161(9):659-67. doi: 10.7326/M13-2908. PMID: 25364887. Accessed October 5, 2020
3. Thiola® [Package insert] San Diego, CA: Retrophin Inc.; January 2021. Available at: [https://thiolaec.com/sites/default/files/pdfs/nda/Thiola\\_PI.pdf](https://thiolaec.com/sites/default/files/pdfs/nda/Thiola_PI.pdf).
4. Tiselius HG. New horizons in the management of patients with cystinuria. Curr Opin Urol. 2010 Mar;20(2):169-73. doi: 10.1097/MOU.0b013e328333b674. PMID: 19887942. Accessed October 5, 2020

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.