



MEDICATION POLICY

Generic Name: Tiopronin

Therapeutic Class or Brand Name: Thiola®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 5/7/15

Date Last Reviewed/Revised: 12/13/17

GPI Code: 5660005000

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

- I. Documented diagnosis of 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.
- IV. Minimum age requirement: 9 years old.

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

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 judgment in providing the most appropriate care for their patients.



MEDICATION POLICY

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. https://www.thiola.com/sites/default/files/2016-11/thiola_pi_unhighlighted.pdf.
2. Medi-Span.

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 judgment in providing the most appropriate care for their patients.



MEDICATION POLICY

<i>Historical Tracking Of Changes Made To Policy</i>	
12/13/2017	1. Updated “ http://www.thiola.com/assets/pdf/ThiolaPrescribingInformation.pdf ” to “ https://www.thiola.com/sites/default/files/2016-11/thiola_pi_unhighlighted.pdf ” under References.
10/7/2016	1. Updated “ http://www.missionpharmcal.com/Global_Content/Package_Inserts/Thiola.pdf ” to “ http://www.thiola.com/assets/pdf/ThiolaPrescribingInformation.pdf ” under References.

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 judgment in providing the most appropriate care for their patients.