

Generic Name: Tiopronin

Therapeutic Class or Brand Name: Thiola

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 5660005000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/7/2015

Date Last Reviewed / Revised: 7/30/2019

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 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. Thiola® [Package insert] San Diego, CA: Retrophin Inc.; June 2019. Available at: https://www.thiola.com/sites/default/files/pdf/NDA_019569_s006_THIOLA_PI_Only_062819.pdf
3. Medi-Span.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
7/30/2019	1. Added "Medical management of kidney stones: AUA guideline" under References.
11/2/2018	1. Policy reviewed: no changes made
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 judgement in providing the most appropriate care for their patients.