

Tiopronin Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Thiola (tiopronin) Thiola (tiopronin) EC Venxxiva (tiopronin) delayed-release	May be subject to quantity limit

APPROVAL CRITERIA

Requests for tiopronin agents (Thiola, Thiola EC, Venxxiva delayed-release) may be approved if the following criteria are met:

- I. Individual has a diagnosis of severe homozygous cystinuria; **AND**
- II. If initiating therapy, individual has urinary cystine concentration greater than 250 mg/L; **AND**
- III. Individual has had a trial and inadequate response to a conservative treatment program including high fluid intake, alkali and diet modification (sodium and protein restriction); **AND**
- IV. Individual will be utilizing in combination with high fluid intake, alkali and diet modification.

Requests for **brand** Thiola or **brand** Thiola EC must meet the following, in addition to the above Prior Authorization criteria:

- I. Individual has failed an adequate trial of one chemically equivalent generic tiopronin agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

- A. Generic tiopronin had inadequate response; **OR**
- B. Generic tiopronin caused adverse outcome; **OR**
- C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Tiopronin agents (Thiola, Thiola EC, Venxxiva delayed-release) may not be approved for the following:

- I. Individuals who are breast feeding.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 10, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Goldfarb DS, Ferraro PM, Sas DJ, et. al. Cystinuria and cystine stones. Last updated: July 15, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 10, 2023.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. Pearle MS, Goldfarb DS, Assimos DG, et. al. American Urological Association. Medical management of kidney stones: AUA guideline. *J Urol*. 2014; 192(2):316-324.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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