



PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Metabolic Disorders – Tiopronin Products Preferred Specialty Management Policy
- Thiola® (tiopronin tablets – Mission Pharmacal, generic)
 - Thiola® EC (tiopronin delayed-release tablets – Mission Pharmacal, generic)
 - Venxxiva® (tiopronin delayed-release tablets – Torrent [generic only])

REVIEW DATE: 02/05/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tiopronin products are indicated, in combination with high fluid intake, alkali, and diet modification, for severe homozygous **cystinuria**, for the prevention of cystine kidney stone formation in adults and pediatric patients ≥ 20 kg, who are not responsive to these measures alone.¹⁻³ Amongst the tiopronin delayed-release formulations, Venxxiva is a branded generic product and is supplied in the same dosage strength as Thiola EC.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one

Preferred Product prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). All approvals are provided for the duration listed in the Metabolic Disorders – Tiopronin Products Prior Authorization Policy.

Documentation: Documentation is required for use of generic tiopronin delayed-release tablets, generic tiopronin tablets, and Venxxiva tablets as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Preferred Products: generic tiopronin delayed-release tablets,
generic tiopronin tablets, Venxxiva tablets
Non-Preferred Products: Thiola EC, Thiola

Metabolic Disorders – Tiopronin Products Preferred Specialty Management Policy non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Thiola EC, Thiola	<p>1. Approve if the patient meets ALL of the following (A, B, <u>and</u> C):</p> <p>A) Patient meets the standard <i>Metabolic Disorders – Tiopronin Products Prior Authorization Policy</i> criteria; AND</p> <p>B) Patient meets ONE of the following (i <u>or</u> ii):</p> <p>i. Patient has tried ONE of generic tiopronin delayed-release tablets or Venxxiva tablets [documentation required]; OR</p> <p>ii. Patient has tried generic tiopronin tablets [documentation required]; AND</p> <p>C) Patient cannot continue to use generic tiopronin or Venxxiva due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescriber, would result in a significant allergy or serious adverse reaction [documentation required].</p> <p>2. For a patient who met criteria 1A but NOT 1B and 1C, approve the Preferred Product.</p>

REFERENCES

1. Thiola® tablets [prescribing information]. San Antonio, TX: Mission Pharmacal; June 2019.

2. Thiola® EC delayed-release tablets [prescribing information]. San Antonio, TX: Mission Pharmacal; March 2021.
3. Venxxiva® delayed-release tablets [prescribing information]. Cambridge, UK: Torrent; December 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 10/21/2024.	08/07/2024
Early Annual Revision	Added Venxxiva, a branded generic tiopronin delayed-release product, to the Policy as a Preferred Product. Updated criteria to include a trial of Venxxiva as an option for approval of the non-preferred product.	02/05/2025

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.