

## Pharmacy Medical Necessity Guidelines: Xuriden™ (uridine triacetate)

Effective: April 14, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p><b>Fax Numbers:</b>  RXUM:  617.673.0988</p>	

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### **FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Xuriden (uridine triacetate) is a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria.

Hereditary orotic aciduria is a rare genetic metabolic disorder, which has been reported in approximately 20 patients worldwide. The condition is due to a defective or deficient enzyme, resulting in the inability of the body to normally synthesize uridine, a necessary component of ribonucleic acid. Signs and symptoms of hereditary orotic aciduria include blood abnormalities (e.g., anemia), urinary tract obstruction, failure to thrive, and developmental delays.

### COVERAGE GUIDELINES

The plan may authorize coverage of Xuriden (uridine triacetate) for members when the following criterion is met:

- Documented diagnosis of hereditary orotic aciduria

### LIMITATIONS

None

### CODES

None

### REFERENCES

- Food and Drug Administration (FDA). FDA approves new orphan drug to treat rare autosomal recessive disorder. September 2015. URL: [fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm457867.htm](http://fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm457867.htm). Available from Internet. Accessed 2016 July 25.
- Xuriden (uridine triacetate) [prescribing information]. Rockville, MD: Wellstat Therapeutics Corporation; 2017 March.

### APPROVAL HISTORY

August 5, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- September 12, 2017: No changes
- October 16, 2018: Administrative update to template
- December 10, 2019: No changes

5. April 14, 2020: Effective March 30, 2020, PA no longer required for Commercial and Direct Plans. MNG only applies to MA and RITogether plans.

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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