MEDICAL MUTUAL®

Drug Policy

Policy:	Xuriden (uridine triacetate)	Annual Review Date: 06/15/2023 Last Revised Date: 06/15/2023

OVERVIEW

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

POLICY STATEMENT

This policy involves the use of Xuriden. Prior authorization is recommended for pharmacy benefit coverage of Xuriden. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of **Xuriden** is recommended in those who meet the following criteria:

1. <u>Hereditary Orotic Aciduria (Orotic Aciduria Type 1)</u>

Criteria. *Approve for 1 year if the patient meets the following criteria (A and B):*

A) Patient has hereditary orotic aciduria confirmed by at least one of the following (i <u>or</u> ii):
- **i.** Molecular genetic testing confirming biallelic pathogenic mutation in the *UMPS* gene; OR
- **ii.** Clinical diagnosis supported by all of the following (a,b and c):
  - **a)** At least one clinical manifestation consistent with orotic aciduria type 1 (i.e. megaloblastic anemia, immunodeficiency, developmental delays, and failure to thrive) ; AND
  - **b)** First-degree family relative (i.e., parent or sibling) with hereditary orotic aciduria; AND
  - **c)** Urinary orotic acid level above the normal reference range for the reporting laboratory; AND

B) Xuriden is prescribed by, or in consultation with, a metabolic specialist, geneticist, or physician specializing in the condition being treated.

Initial Approval/ Extended Approval.
1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xuriden has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Xuriden [prescribing information]. Gaithersburg, MD: Wellstat Therapeutics Corp.; March 2017.
2. Uridine triacetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 10 November 2017. Accessed on 18 June 2019.