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5.30.041

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	February 26, 2016
Subject:	Xuriden	**Page:**	1 of 3

Last Review Date: September 6, 2024

Xuriden

Description

Xuriden (uridine triacetate)

Background
Xuriden is used to treat hereditary orotic aciduria, an extremely rare genetic disorder where the body cannot make uridine due to a deficient enzyme. Uridine is a critical component of ribonucleic acid (RNA), which plays a vital role in countless cell functions. The disease generally manifests itself as blood abnormalities, urinary tract obstruction (due to formation of orotic acid crystals in the urinary tract), failure to thrive, and developmental delays. Xuriden works by replacing uridine so that RNA can continue with its necessary function (1).

Regulatory Status
FDA-approved indication: Xuriden is a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xuriden may be considered **medically necessary** if the conditions indicated below are met.

Xuriden may be considered **investigational** in patients for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Hereditary orotic aciduria

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Xuriden is a pyrimidine analog indicated for hereditary orotic aciduria. Hereditary orotic aciduria is a rare genetic disorder. The safety and effectiveness of Xuriden have been established in pediatric patients with hereditary orotic aciduria (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Xuriden while maintaining optimal therapeutic outcomes.

References

1. Xuriden [package insert]. West Conshohocken, PA:BTG International Inc.; August 2023.

Policy History

Date	Action
February 2016	Addition to PA
March 2016	Annual editorial review
September 2016	Annual editorial review
December 2017	Annual review and reference update
November 2018	Annual review
December 2019	Annual editorial review. Changed approval duration from lifetime to 2 years
December 2020	Annual review and reference update
December 2021	Annual review
December 2022	Annual review. Changed policy number to 5.30.041
September 2023	Annual review
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.