



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE TRIACETATE

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|--------------------|---------|------|-------|------------------------|-----------------|
| URIDINE TRIACETATE | XURIDEN | | 39481 | GPI-10 (3090387520) | |

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary orotic aciduria as confirmed by **ALL** of the following criteria?
 - Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
 - Patient has an elevated urinary orotic acid level according to an age-specific reference range

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at end of the guideline.

2. Is the medication prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases?

If yes, **approve for 6 months by GPID or GPI-10 up to #4 packets per day.**

APPROVAL TEXT: Renewal requires that the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) have stabilized or improved from baseline while on treatment with uridine triacetate.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:

- A. You have hereditary orotic aciduria (HOA: genetic disease where you do not have a type of protein to make a chemical)
- B. Your diagnosis is confirmed by ALL of the following:
 1. Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
 2. Elevated urinary orotic acid levels according to your age-specific reference range
- C. Therapy is prescribed by or given in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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URIDINE TRIACETATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) stabilized or improved from baseline while on treatment with uridine triacetate?

If yes, **approve for 12 months by GPID or GPI-10 up to #4 packets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:

- A. Your age dependent hematologic parameters (blood lab tests) have stabilized or improved from baseline while on treatment with Xuriden (uridine triacetate).

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xuriden.

REFERENCES

- Xuriden [Prescribing Information]. Gaithersburg, MD: Wellstat Therapeutics Corporation. December 2019.

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|---------|------------|-----|
| Library | Commercial | NSA |
| Yes | Yes | No |

Part D Effective: N/A

Commercial Effective: 09/07/20

Created: 02/16

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P&T Approval: 05/16