University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-23 Uridine Triacetate

Effective Date: 4/23/25

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by University of Michigan Health Plan (UM Health Plan) and may not be covered by all UM Health Plan plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact U UM Health Plan Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Vistogard and Xuriden are specialty drugs indicated for very specific diagnoses and are associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses, appropriate severity of symptoms and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Fluoropyrimidine (fluorouracil or capecitabine) overdose or overexposure: Vistogard oral (uridine triacetate).

   A. Diagnosis and severity.

      1. Overdose [must meet one listed below]:

         a. Increased dose.

         b. Increased rate of infusion (1.3-720 times planned administration rate).

   B. Severe or life-threatening toxicity or severe adverse reactions within 96 hours following end of infusion. [must meet one listed below]:

      1. Severe toxicity of grade III or above: cardiac or central nervous system.

2. Severe adverse reactions of grade III or above: Gastrointestinal toxicity of mucositis or diarrhea and/or neutropenia.

C. Dosage regimen.

1. Initiate: as soon as possible within 96 hours post infusion.

2. Dose:

a. Adult: 10 grams orally every six hours times 20 doses.

b. Pediatric: 6.2 grams per m^2 orally (maximum 10 grams per dose) every six hours times 20 doses.

D. Approval.

1. Initial: up to 20 doses over five days.

2. Re-approval: up to 20 doses over five days.

II. Hereditary Orotic Aciduria: Xuriden oral (uridine triacetate).

A. Diagnosis and severity [must meet both listed below]:

1. Severe megaloblastic anemia with normal B12 and folate levels and no transcobalamin-II deficiency.

2. Assay of the transferase and decarboxylase enzymes from the erythrocytes (presumptive diagnosis of urinary orotic acid).

B. Dosage regimen.

1. Initial: 60 mg per Kg once daily.

2. Titrate: increase to 120 mg per Kg for insufficient efficacy [must meet one listed below]:

a. Levels of urinary orotic acid still above normal or increased above the patient's usual range.

b. Lab values Red Blood Cells (RBC) or White Blood Cells (WBC) indices show evidence of worsening.

c. Signs and symptoms of disease worsen.

C. Approval.

1. Initial: six months.

2. Re-approval:

a. Duration: one year

b. Outcome: improvement of lab indices and disease signs and symptoms.

III. Appropriate medication use [must meet one listed below]:

A. Food and Drug Administration (FDA) approval status [must meet one listed below]:

1. FDA approved: product, indication, and/or dosage regimen.

2. Non-FDA approved: compendium support (UpToDate® Lexidrug™) for use of a drug for a non-FDA-approved indication or dosage regimen.

B. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

4.0 Coding:

COVERED PRODUCTS - PHARMACY BENEFIT		
Brand Name	**Generic Name**	**Prior Approval**
Vistogard	uridine triacetate	Y
Xuriden	uridine triacetate	Y

5.0 References, Citations & Resources:

1. Lexi comp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; uridine triacetate, accessed March 2025.
2. Fluorouracil Toxicity and DPYD; Http://emedicine.medscape.com/article/1746057-overview,accessed April 2016.
3. FDA Approves First Emergency Treatment for Chemotherapy Overdose. Oncology Times January 10, 2016; 27.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 06/30/2016

Next Review Date: 05/01/2026

Revision Date	Reason for Revision
7/19	Moved to the new format; replaced abbreviations
8/20	Annual review, no changes
8/21	Annual review added appropriate use section, clarified criteria instructions, replaced symbols
2/22	Annual review, formatting, D Lucas updated spelling
10/22	Annual review; no change
2/23	Annual review; No change
2/24	Annual review; updated coding, removed Appendix I: Patient Safety & Monitoring
2/25	Annual review; updated reference