Pharmacy Benefit Determination Policy

Policy Subject: Uridine Triacetate	**Dates:**
Policy Number: SHS PBD3	**Effective Date:** June 30, 2016
Category: Antidote	**Revision Date**
Policy Type: ☐ **Medical** ☒ **Pharmacy**	**Approval Date:** October 24, 2018
Department: Pharmacy	**Next Review Date:** October 2019
Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	PHP: Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Vistogard and Xuriden through the Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

Clinical Determination Guidelines:

Document the following with chart notes

A. Fluoropyrimidine (fluorouracil or capecitabine) overdose or overexposure: Vistogard
   1. Diagnosis and severity
      a. Overdose:
         - Increased dose or
         - 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:
         - Severe toxicity (≥ grade III): Cardiac or CNS
         - Severe adverse reactions (≥ grade III): GI toxicity (mucositis, diarrhea) and/or neutropenia
   2. Dosage regimen
      a. Initiate: As soon as possible; within 96 hours post infusion
      b. Dose
         - Adult: 10gm oral every 6 hours x 20 doses
         - Pediatric: 6.2gms/m^2 oral (max 10gms/dose) every 6 hours times 20 doses

B. Hereditary Orotic Aciduria: Xuriden
   1. Diagnosis and severity
      a. Severe megaloblastic anemia w normal B12 and folate levels and no TC-II deficiency
      b. Assay of the transferase & decarboxylase enzymes from the erythrocytes (presumptive dx - urinary orotic acid)
   2. Dosage regimen
      a. Initial: 60mg/Kg once daily
      b. Titrate: Increase to 120mg/Kg for insufficient efficacy (1 of the below)
         - Levels of urinary orotic acid still above normal or ↑above patient usual range
         - Lab values (RBC or WBC indices) show evidence of worsening
         - Signs and symptoms of disease worsen
   3. Approval
      a. Initial: 6 months
      b. Re-approval: 1 year (Improvement of lab indices and disease signs and symptoms)

Appendix I: Patient Safety & Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Vistogard Xuriden uridine triacetate	• GI: Vomiting (10%), nausea (5%), diarrhea (3%)	Fluorouracil/capecitabine overdose GI: GI toxicity Labs: CBC w differential	None

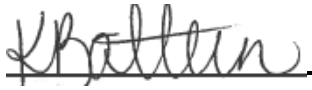
References and Resources:

1. Lexicomp Online® , Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.; uridine triacetate, accessed September 2018
2. Flourouracil 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.

Approved By:

10/24/18

Peter Graham, MD – PHP Executive Medical Director — Date



10/24/18

Human Resources – Kurt Batteen — Date