PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vistogard Prior Authorization Policy
- Vistogard® (uridine triacetate oral granules – Wellstat Therapeutics)

REVIEW DATE: 07/29/2020

OVERVIEW

Vistogard, a pyrimidine analog, is indicated for the emergency treatment of adult and pediatric patients:
- Following a fluorouracil or capecitabine overdose regardless of the presence of symptoms; or
- Who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity, neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration.[1]

As a limitation of use, Vistogard is not recommended for the non-emergent treatment of adverse events associated with fluorouracil or capecitabine because it may diminish the efficacy of these drugs.[1] Additionally, the safety and efficacy of Vistogard initiated more than 96 hours following the end of fluorouracil or capecitabine administration have not been established. Vistogard is supplied in 10 gram packets. For adults, the dose is 10 grams (1 packet) every 6 hours for 20 doses. For pediatric patients, the dose is 6.2 grams/m^2 of body surface area (not to exceed 10 grams per dose) every 6 hours for 20 doses. Any unused portion of a packet must be discarded; it should not be saved for subsequent doses.

Disease Overview

Fluorouracil and capecitabine (a fluorouracil prodrug) are widely used chemotherapeutic agents with potential for significant toxicity. Exaggerated sensitivity to capecitabine or fluorouracil may occur due to genetic variations in certain enzymes, renal impairment, or other causes.[2] Toxicity results in tissue damage, often manifesting as ulcerative mucositis with neutropenia leading to sepsis, shock, and organ failure. Additionally, central neurotoxicity and cardiac toxicity may occur without any identifiable predisposing factors. Exogenous uridine competes with the toxic metabolite fluorouridine triphosphate for incorporation into RNA in normal tissues, thereby protecting the tissues from toxicity.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Vistogard. All approvals are provided for the duration noted below.

Automation: None

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Capecitabine or Fluorouracil Overdose.** Approve for 7 days.

2. **Capecitabine or Fluorouracil Toxicity, Severe or Life-Threatening.** Approve for 7 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vistogard is not recommended in the following situations:

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

REFERENCES

1. Vistogard® oral granules [prescribing information]. Rockville, MD: Wellstat Therapeutics; February 2017.
2. Ma WW, Saif MW, El-Rayes BF, et al. Emergency use of uridine triacetate for the prevention and treatment of life-threatening 5-fluorouracil and capecitabine toxicity. *Cancer.* 2017;123(2):345-356.