DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Vistogard Drug Quantity Management Policy – Per Rx
- Vistogard® (uridine triacetate oral granules – Wellstat)

REVIEW DATE: 03/27/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Vistogard, a pyrimidine analog, is indicated for the emergency treatment of adults and pediatric patients for the following uses:[1]

- **Fluorouracil or capecitabine overdose**, regardless of the presence of symptoms.
- **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.

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]

Dosing

For adults, the recommended dosage is 10 grams (1 packet) orally every 6 hours for 20 doses, without regard to meals. For pediatric patients, the recommended dosage is 6.2 grams/m^2 body surface area (not to exceed 10 grams/dose) orally

every 6 hours for 20 doses, without regard to meals. Discard any unused portion of the granules; do not leave granules left in the open packet for subsequent dosing.

It is noted that if a patient vomits within 2 hours of taking a dose of Vistogard, initiate another complete dose as soon as possible after the vomiting episode. Administer the next dose at the regularly scheduled time.

Availability

Vistogard is supplied as oral granules in 10 gram single-dose packets. Packets are supplied in cartons containing either four or 20 packets per carton.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Vistogard. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Drug Quantity Limits

Product	Package Size	Retail or Home Delivery Maximum Quantity per Rx
Vistogard® (uridine triacetate oral granules)	10 gram packets (cartons of 4 packets and cartons of 10 packets)	20 packets*

* This is enough drug to cover one complete course of therapy (20 doses).

Oncology – Vistogard Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If a patient requires additional dosing due to vomiting within 2 hours of taking a Vistogard dose, approve a one-time override of 4 additional packets at retail or home delivery.

REFERENCES

1. Vistogard® oral granules [prescribing information]. Rockville, MD: Wellstat; March 2016.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. **10 gram packets (4 packet cartons and 20 packet cartons):** Home delivery quantity limit was changed from 60 packets to 20 packets per dispensing.	03/22/2023
Annual Revision	No criteria changes.	03/27/2024