

# QUANTITY LIMIT CRITERIA

## DRUG CLASS

ANTIEMETICS

## BRAND NAME (generic)

(granisetron hydrochloride) (ALL PRODUCTS)

**SANCUSO**

(granisetron transdermal system)

**SUSTOL**

(granisetron extended-release injection)

**Status: CVS Caremark® Criteria**

**Type: Quantity Limit**

## POLICY

### FDA-APPROVED INDICATIONS

#### **Granisetron Hydrochloride**

##### Granisetron Hydrochloride Tablets

Granisetron hydrochloride tablets USP are indicated for the prevention of:

- Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

##### Granisetron Hydrochloride Injection:

Granisetron hydrochloride injection, USP is a serotonin-3 (5-HT3) receptor antagonist indicated for:

- The prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- The prevention and treatment of postoperative nausea and vomiting in adults. As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided during the postoperative period, granisetron hydrochloride injection USP is recommended even where the incidence of postoperative nausea and/or vomiting is low.

#### **Sancuso Transdermal System**

Sancuso is indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration.

#### **Sustol Extended-Release Injection**

Sustol is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

## INITIAL LIMIT QUANTITY

Granisetron, Sancuso, Sustol Limit Policy 01-2024.docx

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**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength**

<b><u>Drug</u></b>	<b><u>4 Week Limit*</u></b>	<b><u>12 Week Limit**</u></b>
Granisetron Hydrochloride Tablets	12 tablets / 21 days	Does Not Apply*
Granisetron Hydrochloride Injection 1 mg / mL or 4mg/4mL	2 mL / 21 days	Does Not Apply*
Sancuso (granisetron transdermal system)	2 patches / 21 days	Does Not Apply*
Sustol (granisetron extended-release injection 10 mg / 0.4 mL)	0.8 mL / 21 days	Does Not Apply*

\* The duration of 21 days is used for a 28-day fill period to allow time for refill processing.

**\*\* These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3-month supplies filled.**

## **REFERENCES**

1. Granisetron Hydrochloride Tablet [package insert]. Berlin, CT: Breckenridge Pharmaceutical, Inc.; October 2019.
2. Granisetron Hydrochloride Injection [package insert]. E. Windsor, NJ: AuroMedics Pharma LLC; December 2021.
3. Sancuso Patch [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; December 2022.
4. Sustol Injection [package insert]. San Diego, CA: Heron Therapeutics, Inc.; May 2023.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed November 29, 2023.
6. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2023).
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/antiemesis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf). Accessed November 30, 2023.