SmartHealth

Ascension

Granisetron Extended Release

(Sustol®) J1627

Granisetron extended release injection (Sustol®) may be authorized when the following criteria are met:

- Prevention of acute or delayed chemotherapy induced nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy; **OR**
- Prevention of acute or delayed chemotherapy induced nausea and vomiting associated with initial or repeat courses of highly emetogenic chemotherapy and use is in combination with an NK1 antagonist (e.g., fosaprepitant, aprepitant, rolapitant) or the individual has a contraindication or intolerance to an NK1 antagonist; **OR**
- Prevention of acute or delayed chemotherapy induced nausea and vomiting associated with initial or repeat courses of low emetogenic chemotherapy and the individual had an inadequate response or contraindication to use of an alternative formulation of a serotonin antagonist (e.g., oral ondansetron, granisetron) to prevent chemotherapy-induced nausea and vomiting with the current regimen;

AND

- The individual had an inadequate response or contraindication to palonosetron; **AND**
- Use is in combination with dexamethasone or the individual has a contraindication or intolerance to dexamethasone; **AND**
- Individual is not receiving an additional serotonin antagonist (e.g., palonosetron, granisetron transdermal); **AND**
- Dose is 10 mg administered subcutaneously in combination with dexamethasone at least 30 minutes before the initiation of MEC or AC combination chemotherapy; **AND**
- Dose is administered on Day 1 of chemotherapy and not more frequently than once every 7 days because of the extended-release properties of the formulation.

Exclusion Criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Step/Alternative Therapies:

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
Ondansetron (Zofran) [J2405]	Granisetron Extended Release
Palonosetron (Aloxi) [J2469]	
Granisetron (Kytril) [J1626]	

Duration of approval: 6 months

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

Sustol® is a serotonin-3 (5-HT3) receptor antagonist 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.

References:

Ascension Hematology & Oncology Expert Review Panel. (2021, March 30). *Chemotherapy Induced Nausea and Vomiting (CINV) Guidelines*. Ascension TAG INITIATIVES - PSWP.

Sustol® (granisetron extended release inj) label. (2016, August). Accessdata.fda.gov. Retrieved April 26, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022445s000lbl.pdf

National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines for Antiemesis.* (2022, March 23) NCCN Retrieved April 22, 2022, from https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.