Granisetron (Sustol®) extended release injection

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 10/4/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of Granisetron. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Granisetron is a selective 5-hydroxytryptamine3 (5-HT3) receptor antagonist with little or no affinity for other serotonin receptors, including 5-HT1, 5-HT1A, 5-HT1B/C, 5-HT2; for alpha1-, alpha2-, or beta-adrenoreceptors; for dopamine-D2; or for histamine-H1; benzodiazepine; picrotoxin or opioid receptors. Serotonin receptors of the 5-HT3 type are located peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. During chemotherapy that induces vomiting, mucosal enterochromaffin cells release serotonin, which stimulates 5-HT3 receptors. This evokes vagal afferent discharge, inducing vomiting. Animal studies demonstrate that, in binding to 5-HT3 receptors, granisetron blocks serotonin stimulation and subsequent vomiting after emetogenic stimuli such as cisplatin.

FDA Indications[1]

Granisetron (Sustol®) is FDA indicated for the following:

- 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.

NCCN Compendium Supported Indications[2]

Use in combination with dexamethasone before parenteral anticancer therapy with

- High emetic risk with olanzapine and either aprepitant (PO or IV), fosaprepitant, or rolapitant (all preferred)
- High emetic risk with either aprepitant (PO or IV), fosaprepitant, or rolapitant

Coverage Determinations[1,2]

Granisetron (Sustol®) will require prior authorization. This agent is considered medically necessary for the following oncology-related indications if all criteria below are met:

Prophylaxis of Chemotherapy-Induced Nausea and Vomiting

- The member will be receiving parenteral anticancer therapy associated with moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens **AND**
- Use is in combination with dexamethasone or the member has a contraindication or intolerance to dexamethasone **AND**
- Use is for the prevention of acute or delayed chemotherapy induced nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy or anthracycline and cyclophosphamide (AC)

Recommended dosage:

10 mg SC (extended-release injection) at least 30 minutes prior to chemotherapy on day 1; do not administer more frequently than once every 7 days.

Prophylaxis of Chemotherapy-Induced Nausea and Vomiting

- The member will be receiving parenteral anticancer therapy associated with highly emetogenic chemotherapy (HEC) **AND**
- Use is in combination with dexamethasone or the member has a contraindication or intolerance to dexamethasone **AND**
- Use is for the 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 member has a contraindication or intolerance to an NK1 antagonist

Recommended dosage:

10 mg SC (extended-release injection) at least 30 minutes prior to chemotherapy on day 1; do not administer more frequently than once every 7 days.

All indications:

- Granisetron (Sustol®) will be approved through clinical review up to a 12-month determination.

Coverage Limitations

Treatment with Granisetron (Sustol®) is not considered medically necessary for members with the following concomitant conditions:

- Sustol® has not been studied for the treatment of established nausea and vomiting.
- Granisetron extended release may not be used concurrently (other 5-HT3 antagonist drugs should not be used within 7 days following a granisetron extended release dose) with other 5-HT3 antagonists unless a change of therapy is warranted.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary.

Contraindications/Warnings/Precautions[1]

- Hypersensitivity to granisetron, any of the components of Sustol®, or to any of the other 5-HT_3 receptor antagonists
- Warnings/precautions:
    - Injection site reactions, including infection, bleeding, pain, nodules, swelling, and induration
    - Gastrointestinal disorders
    - Hypersensitivity reactions
    - Serotonin syndrome

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: Injection, granisetron, extended-release, 0.1 mg
    - J1627

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines

may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Granisetron [package insert]. Heron Therapeutics, Inc., Redwood City, CA. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022445s000lbl.pdf
2. Granisetron extended release subcutaneous injection. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Schnadig ID, Agajanian R, Dakhil C, et al. APF530 (granisetron injection extended- release) in a three-drug regimen for delayed CINV in highly emetogenic chemotherapy. Future Oncol. 2016;12:1469-1481.