

Sustol® (granisetron extended-release) (Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 6 months and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Sustol Extended-Release Injection 10 mg/0.4 mL single-dose pre-filled syringe: 1 syringe per 7 day supply

B. Max Units (per dose and over time) [HCPCS Unit]:

- 100 billable units per 7 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient must be at least 18 years of age; **AND**

Prevention of chemotherapy-induced nausea and vomiting (CINV) † ^{1,3-6}

- Must be administered in combination with dexamethasone; **AND**
- Patient is receiving highly emetogenic chemotherapy (HEC)* or a regimen that is not considered to be HEC*; **AND**
- Patient has failed** with palonosetron while receiving the current chemotherapy regimen; **AND**
- Sustol is NOT covered for any of the following:
 - Breakthrough emesis
 - Repeat dosing in multi-day emetogenic chemotherapy regimens

*Highly emetogenic chemotherapy (HEC):

| Highly Emetogenic Chemotherapy (HEC) | | | |
|---|-----------------|--|--|
| Carboplatin | Carmustine | Cisplatin | Cyclophosphamide |
| Dacarbazine | Doxorubicin | Epirubicin | Fam-trastuzumab deruxtecan-nxki |
| Ifosfamide | Mechlorethamine | Melphalan ≥ 140 mg/m ² | Sacituzumab govitecan- hziy |
| Streptozocin | | | |
| The following can be considered HEC in certain patients | | | |
| Dactinomycin | Daunorubicin | Idarubicin | Irinotecan |
| Methotrexate ≥ 250 mg/m ² | Oxaliplatin | Trabectedin | |
| The following regimens can be considered HEC | | | |
| FOLFOX | FOLFIRI | FOLFIRINOX; FOLFOXIRI | AC (any anthracycline + cyclophosphamide) |

**** Failure is defined as:**

- Two or more documented episodes of vomiting attributed to the current chemotherapy regimen

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

| Indication | Dose |
|--|--|
| Prevention of chemotherapy-induced nausea and vomiting in adults | 10 mg, administered subcutaneously by a healthcare provider, on Day 1 of chemotherapy; not more frequently than once every 7 days. |

VI. Billing Code/Availability Information

HCPCS code:

- J1627 – Injection, granisetron, extended-release, 0.1 mg; 1 billable unit = 0.1 mg

NDC:

- Sustol Extended-Release Injection 10 mg/0.4 mL single-dose pre-filled syringe: 47426-0101-xx

VII. References

1. Sustol [package insert]. San Diego, CA; Heron Therapeutics; May 2017. Accessed March 2023.
2. 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
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2023.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for granisetron extended release subcutaneous system. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. March 2023.
5. Roila F, Molassiotis A, Herrstedt J, et al. MASCC and ESMO Consensus Guidelines for the Prevention of Chemotherapy and Radiotherapy-Induced Nausea and Vomiting: ESMO Clinical Practice Guidelines. *Ann Oncol* (2016) 27 (suppl 5): v119-v133.
6. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Guideline Update. *J Clin Oncol.* 2020 Aug 20;38(24):2782-2797. Doi: 10.1200/JCO.20.01296.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|-----------------------------------|
| R11.0 | Nausea |
| R11.10 | Vomiting, unspecified |
| R11.11 | Vomiting without nausea |
| R11.12 | Projectile vomiting |
| R11.2 | Nausea with vomiting, unspecified |

| ICD-10 | ICD-10 Description |
|----------|--|
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter |
| T45.1X5D | Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter |
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs, sequela |
| T45.95XA | Adverse effect of unspecified primarily systemic and hematological agent, initial encounter |
| T45.95XD | Adverse effect of unspecified primarily systemic and hematological agent, subsequent encounter |
| T45.95XS | Adverse effect of unspecified primarily systemic and hematological agent, sequela |
| T50.905A | Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter |
| T50.905D | Adverse effect of unspecified drugs, medicaments and biological substances, subsequent |
| T50.905S | Adverse effect of unspecified drugs, medicaments and biological substances, sequela |
| Z51.11 | Encounter for antineoplastic chemotherapy |
| Z51.12 | Encounter for antineoplastic immunotherapy |

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article(s) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|---------------------|--------------------------------------|-------------------------|
| 15 | KY, OH | CGS Administrators, LLC |