# Sustol® (granisetron extended-release)
## (Subcutaneous)

Document Number: IC-0283

**Last Review Date: 04/03/2019**
**Date of Origin:** 08/30/2016
**Dates Reviewed: 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 04/2018, 04/2019**

## I. Length of Authorization

Coverage is provided for six months and may NOT be renewed.

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [Pharmacy Benefit]:**

– Sustol Extended-Release Injection 10 mg/0.4 mL syringe: 1 syringe per 7 day supply

**B. Max Units (per dose and over time) [Medical Benefit]:**

- 100 billable units per 7 days

## III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prevention of chemotherapy-induced nausea and vomiting (CINV) †

- Patient must be at least 18 years of age; AND
- 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:
  - Breakthrough emesis; OR
  - Repeat dosing in multi-day emetogenic chemotherapy regimens

*Highly emetogenic chemotherapy (HEC):

| Highly Emetogenic Chemotherapy (HEC) | | | |
|---|---|---|---|
| Carboplatin | Carmustine | Cisplatin | Cyclophosphamide |
| Dacarbazine | Doxorubicin | Epirubicin | Ifosfamide |

| | | | |
|---|---|---|---|
| Mechlorethamine | Streptozocin | | |
| **The following chemotherapy can be considered HEC in certain patients:** | | | |
| Dactinomycin | Daunorubicin | Irinotecan | Methotrexate ≥ 250 mg/m$^2$ |
| Oxaliplatin | Trabectedin | | |
| **The following regimen can be considered HEC:** | | | |
| FOLFOX | | | |

** Failure is defined as:

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

† FDA-approved indication(s)

## IV. Renewal Criteria

Coverage cannot be renewed.

## V. Dosage/Administration

| 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

Jcode:

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 February 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 3.2018. National Comprehensive Cancer Network, 2019. 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 February 2019.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for granisetron extended release subcutaneous system. National Comprehensive Cancer Network, 2019. 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. February 2019.

## 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 |
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter |
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs, sequela |
| T45.95XA | Adverse effect of unspecified primarily systemic and hematological agent, initial encounter |
| T50.905A | Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter |
| 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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-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): 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. |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| 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) |
| 15 | KY, OH | CGS Administrators, LLC |