

Sustol[®] (granisetron extended-release) (Subcutaneous)

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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)*; **AND**
 - Patient has failed** with palonosetron while receiving the current chemotherapy regimen; **OR**
 - Patient is receiving a regimen that is not considered to be HEC; **AND**
 - Patient has failed** with BOTH of the following while receiving the current chemotherapy regimen:
 - Ondansetron (Zofran) or granisetron (Kytril); **AND**
 - Palonosetron; **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 $\geq 250\text{mg/m}^2$
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 March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 2.2017. National Comprehensive Cancer Network, 2017. 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 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for granisetron extended release subcutaneous system. National Comprehensive Cancer Network, 2018. 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 2018.

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.
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