

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

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

Document Number: MH-0283

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Effective Date: 01/01/2023

I. Length of Authorization

Coverage is provided for six 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 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 ^{1,3,4,5,6}

Medicare members may be subject to alternative step therapy criteria

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) †

- 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	Melphalan	Sacituzumab govitecan	Streptozocin
The following chemotherapy can be considered HEC in certain patients:			
Dactinomycin	Daunorubicin	Irinotecan	Methotrexate ≥ 250 mg/m ²
Oxaliplatin	Trabectedin	Idarubicin	
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)

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

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 2021.
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 1.2021. National Comprehensive Cancer Network, 2021. 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 2021.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for granisetron extended release subcutaneous system. National Comprehensive Cancer Network, 2021. 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 2021.
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 Clinical Practice Guideline Update. *J Clin Oncol.* 2017 Oct 1;35(28):3240-3261.

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

ICD-10	ICD-10 Description
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