Sustol® (granisetron extended-release) (Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

- 100 billable units per 7 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

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

Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) † ‡ [1,3-6]

- Member has failed**§** with palonosetron while receiving the current anticancer chemotherapy regimen; **AND**
  - Used in combination with dexamethasone; **AND**
    - Member is receiving highly emetogenic anticancer chemotherapy (HEC)*; **AND**
      - Used in combination with either aprepitant (PO or IV), fosaprepitant, or rolapitant with or without olanzapine; **OR**
    - Member is receiving moderately emetogenic anticancer chemotherapy (MEC)**; or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens**; OR**
  - Used in combination with olanzapine, neurokinin-1 receptor antagonist (NK-1 RA), and dexamethasone as a component of a 4-drug regimen if not previously given; **AND**
    - Member experienced emesis during a previous cycle of anticancer chemotherapy with a 3-drug regimen (olanzapine or NK-1 RA-containing regimen); **OR**
    - Member has additional risk factors for anticancer agent-induced nausea/vomiting **¥**; **AND**
- Sustol is NOT covered for any of the following:
  - Breakthrough emesis

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- Repeat dosing in multi-day emetogenic chemotherapy regimens (more frequently than once every 7 days)

§ NOTE: Failure is defined as two or more documented episodes of vomiting attributed to the current chemotherapy regimen

***Highly emetogenic chemotherapy (HEC)**:

Highly Emetogenic Chemotherapy (HEC) [3]			
Busulfan^	Carboplatin AUC ≥4	Carmustine >250 mg/m^2	Cisplatin
Cyclophosphamide >1500 mg/m^2	Dacarbazine	Datopotamab deruxtecan-dlnk	Doxorubicin ≥60 mg/m^2
Epirubicin >90 mg/m^2	Fam-trastuzumab deruxtecan-nxki	Ifosfamide ≥2 g/m^2 per dose	Mechlorethamine
Melphalan^	Sacituzumab govitecan-hziy	Streptozocin	Thiotepa^
Zolbetuximab-clzb			
The following can be considered HEC in certain members [3]			
Carboplatin AUC < 4	Carmustine ≤250 mg/m^2	Cyclophosphamide ≤1500 mg/m^2	Dactinomycin
Daunorubicin	Doxorubicin <60 mg/m^2	Epirubicin ≤90 mg/m^2	Idarubicin
Ifosfamide <2 g/m^2 per dose	Irinotecan	Methotrexate ≥250 mg/m^2	Oxaliplatin
Trabectedin			
The following regimens can be considered HEC [3]			
FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)

^Note: These agents should be considered highly emetogenic chemotherapy (HEC) when used in the hematopoietic cell transplant (HCT) setting

****Moderately emetogenic chemotherapy (MEC)**:

Moderately Emetogenic Chemotherapy (MEC) [3]			
Aldesleukin >12–15 million IU/m^2 or 600,000 IU/kg	Bendamustine	Clofarabine	Cytarabine >200 mg/m^2
Dinutuximab	Dual-drug liposomal encapsulation of cytarabine and daunorubicin	Irinotecan (liposomal)	Lurbinectedin
Mirvetuximab soravtansine-gynx	Naxitamab-gqgk	Romidepsin	Temozolomide

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Treosulfan			

¥ Member risk factors for anticancer agent-induced nausea/vomiting [3]
• Younger age • Female sex • Previous history of anticancer agent-induced nausea and vomiting (chemotherapy-induced nausea and vomiting [CINV]) • Little or no previous alcohol use • Prone to motion sickness • History of morning sickness during pregnancy • Anxiety/high pretreatment expectation of nausea • Less than 7 hours of sleep the night before chemotherapy • Partial or complete bowel obstruction • Vestibular dysfunction • Brain metastases • Electrolyte imbalance: hypercalcemia, hyperglycemia, or hyponatremia • Uremia • Concomitant drug treatments, including opioids • Supplements/herbal products • Gastroparesis: tumor or chemotherapy (e.g., vincristine) induced or other causes (e.g., diabetes) • Excessive secretions (e.g., seen in members with head and neck cancers) • Malignant ascites • Psychophysiologic: Anxiety or anticipatory nausea/vomiting • Cannabinoid hyperemesis syndrome • Rapid opioid withdrawal • Pancreatitis • Dysmotility • Concomitant radiation therapy (RT), especially total body irradiation (TBI) and RT directed at the abdomen or brain

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

IV. Renewal Criteria [1]

Duration of authorization has not been exceeded (*refer to section I*).

V. Dosage/Administration [1]

Indication	Dose
Prevention of chemotherapy-induced nausea and vomiting (CINV)	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

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VII. References

1. Sustol [package insert]. San Diego, CA; Heron Therapeutics; February 2026. Accessed May 2026.
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 1.2026. National Comprehensive Cancer Network, 2026. 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 May 2026.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for granisetron extended release subcutaneous system. National Comprehensive Cancer Network, 2026. 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. May 2026.
5. Ruhlmann, C.H., Jordan, K., Jahn, F. *et al.* 2023 Updated MASCC/ESMO Consensus Recommendations: prevention of radiotherapy- and chemoradiotherapy-induced nausea and vomiting. *Support Care Cancer* 32, 26 (2024). https://doi.org/10.1007/s00520-023-08226-z
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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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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
T45.1X5D	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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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		
Jurisdictio	**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)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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

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