Granisetron
Policy Number: C4227-C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
5/1/2013	12/18/2019	12/18/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J1627- Sustol	RxPA	Q1 2020 20200122C4227-C

PRODUCTS AFFECTED:
Granisetron, Granisetron solution for injection, Sancuso, Sustol

DRUG CLASS:
Anti-emetics, 5HT3 Receptor Antagonists

ROUTE OF ADMINISTRATION:
Oral or IV injection, Transdermal

PLACE OF SERVICE:
Intravenous- infusion center (buy & bill/specialty pharmacy; not for self-administration), Transdermal/Oral; retail pharmacy

AVAILABLE DOSAGE FORMS:
Granisol 2 mg/10 mL oral solution, Granisetron oral tablets: 1 mg and Granisetron solution for injection: 0.1 mg/mL, 1 mg/mL, 4 mg/mL

FDA-APPROVED USES:
Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin, Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Chemotherapy induced nausea and vomiting, radiation induced nausea and vomiting

REQUIRED MEDICAL INFORMATION:
A. FOR ALL INDICATIONS:
1. Documentation of the treatment plan including the names all of chemotherapy agents; frequency; length, cycle and duration of therapy
   AND
2. Documentation of a moderate or high emetagentic chemo regimen or break through nausea/vomitting on lower risk regimen
   AND

AND

3. FOR SANCUSO AND SUSTOL: Documenation of a trial/failure of granisetron OR ondansetron oral tablet OR IV granisetron

DURATION OF APPROVAL:
Initial authorization: up to 3 months (or length of approved chemotherapy),
Continuation of Therapy: up to 3 months (or length of approved chemotherapy)

QUANTITY:
Tablets: 12 tablets per 21 days
Injection: 2 mL per 21 days
Tansdermal: 1 patch per 21 days
Sustol: 0.8ml per 21 days

PRESCRIBER REQUIREMENTS:
None specified

AGE RESTRICTIONS:
2 years of age and older, Sustol- 18 years of age and older, Sancuso- ages 18 through 64 years of age.

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
1. Medical records showing ongoing chemotherapy or radiation treatment
AND
2. The prescribed medication is effective and well tolerated

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other use of granisetron are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Granisetron is contraindicated in patients who have known hypersensitivity to granisetron or any component of the formulation

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:
None

APPENDIX:

EMETOGENIC POTENTIAL OF PARENTERAL ANTICANCER AGENTS[a]

LEVEL	AGENT		
High emetic risk (>90% frequency of emesis)[b,c]	• AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide • Carboplatin AUC ≥4	• Carmustine >250 mg/m² • Cisplatin • Cyclophosphamide >1,500 mg/m² • Dacarbazine • Doxorubicin ≥60 mg/m²	• Epirubicin >90 mg/m² • Ifosfamide ≥2 g/m² per dose • Mechlorethamine • Streptozocin
Moderate emetic risk (>30%–90% frequency of emesis)[b,c]	• Aldesleukin >12–15 million IU/m² • Amifostine >300 mg/m² • Arsenic trioxide • Azacitidine • Bendamustine • Busulfan • Carboplatin AUC <4[d] • Carmustine[d] ≤250 mg/m² • Clofarabine • Cyclophosphamide ≤1500 mg/m²[d] • Cytarabine >200 mg/m²	• Dactinomycin[d] • Daunorubicin[d] • Dual-drug liposomal encapsulation of cytarabine and daunorubicin • Dinutuximab • Doxorubicin[d] <60 mg/m² • Epirubicin[d] ≤90 mg/m² • Idarubicin • Ifosfamide[d] <2 g/m² per dose • Interferon alfa ≥10 million IU/m² • Irinotecan[d]	• Irinotecan (liposomal) • Melphalan • Methotrexate[d] ≥250 mg/m² • Oxaliplatin[d] • Temozolomide • Trabectedin[d]

Adapted with permission from:
Hesketh PJ, Kris MG, Grunberg SM, et al. Proposal for classifying the acute emetogenicity of cancer chemotherapy. J Clin Oncol 1997;15:103-109.
Grunberg SM, Warr D, Gralla RJ, et al. Evaluation of new antiemetic agents and definition of antineoplastic agent emetogenicity--state of the art. Support Care Cancer 2011;19:S43-47.

[a] Potential drug interactions between antineoplastic agents/antiemetic therapies and various other drugs should always be considered.

EMETOGENIC POTENTIAL OF PARENTERAL ANTICANCER AGENTS[a]

LEVEL	AGENT			
Low emetic risk (10%–30% frequency of emesis)[b,e]	• Ado-trastuzumab emtansine • Aldesleukin ≤12 million IU/m² • Amifostine ≤300 mg/m² • Axicabtagene ciloleucel[f] • Belinostat • Brentuximab vedotin • Cabazitaxel • Carfilzomib • Copanlisib • Cytarabine (low dose) 100–200 mg/m²	• Docetaxel • Doxorubicin (liposomal) • Eribulin • Etoposide • 5-Fluorouracil (5-FU) • Floxuridine • Gemcitabine • Gemtuzumab ozogamicin • Inotuzumab ozogamicin • Interferon alfa >5 - <10 million international units/m²	• Ixabepilone • Methotrexate >50 mg/m² - <250 mg/m² • Mitomycin • Mitoxantrone • Necitumumab • Olaratumab • Omacetaxine • Paclitaxel • Paclitaxel-albumin • Pemetrexed	• Pentostatin • Pralatrexate • Romidepsin • Talimogene laherparepvec • Thiotepa • Tisagenlecleucel[f] • Topotecan • Ziv-aflibercept
Minimal emetic risk (<10% frequency of emesis)[b,e]	• Alemtuzumab • Atezolizumab[g] • Avelumab[g] • Asparaginase • Bevacizumab • Bleomycin • Blinatumomab • Bortezomib • Cetuximab • Cladribine • Cytarabine <100 mg/m²	• Daratumumab • Decitabine • Denileukin diftitox • Dexrazoxane • Durvalumab[g] • Elotuzumab • Fludarabine • Interferon alpha ≤5 million IU/m² • Ipilimumab[g] • Methotrexate ≤50 mg/m²	• Nelarabine • Nivolumab[g] • Obinutuzumab • Ofatumumab • Panitumumab • Pegaspargase • Peginterferon • Pembrolizumab[g] • Pertuzumab • Ramucirumab • Rituximab	• Rituximab and hyaluronidase human injection for SQ use • Siltuximab • Temsirolimus • Trastuzumab • Valrubicin • Vinblastine • Vincristine • Vincristine (liposomal) • Vinorelbine

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Grunberg SM, Warr D, Gralla RJ, et al. Evaluation of new antiemetic agents and definition of antineoplastic agent emetogenicity--state of the art. Support Care Cancer 2011;19:S43-47.
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NCCN & ASCO Antiemetic Guidelines LINK

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Granisetron injection [prescribing information]. Schaumburg, IL: Sagent; February 2016.
2. Sancuso (granisetron transdermal) [prescribing information]. Bedminster, NJ: Kyowa Kirin; January 2017.
3. Sustol (granisetron) extended-release injection [prescribing information]. Redwood City, CA: Heron Therapeutics; November 2016.
4. National Comprehensive Cancer Network. Antiemesis Guidelines (version1.2019). https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf
5. Yarker YE and McTavish D, "Granisetron. An Update of Its Therapeutic Use in Nausea and Vomiting Induced by Antineoplastic Therapy," Drugs, 1994, 48(5):761-93.