Sancuso (granisetron) Patch

Summary

Chemotherapy-induced nausea and vomiting is one of the most distressing symptoms of chemotherapy. Nausea and vomiting are one of the most common side effects of chemotherapy, and while this can occur in those receiving cancer-related radiation and surgery, chemotherapy-induced nausea and vomiting (CINV) is potentially the most severe. There are three distinct types of CINV: acute emesis, occurring within 1-2 hours of chemotherapy; delayed emesis, occurring more than 24 hours after chemotherapy; and, anticipatory emesis, occurring prior to chemotherapy administration as a conditioned response by the individual who has previously experienced nausea and/or vomiting from prior chemotherapy exposures. The goal of managing CINV is preventing it entirely, thus a typical

regimen will include several drugs from different classes administered 1-2 days prior to chemotherapy and 1-2 days after the last chemotherapy administration day (e.g., in a multi-day chemotherapy regimen). The classes of drugs most broadly accepted as having the highest therapeutic index for management of CINV include the type-three 5-hydroxytryptamine (5-HT3) receptor antagonists (e.g. ondansetron, dolasetron, granisetron, palonosetron), the neurokinin-1 receptor (NK1R) antagonists (e.g., aprepitant, fosaprepitant, rolapitant) and glucocorticoids (e.g., dexamethasone).

Sancuso (granisetron) patch is a transdermal formulation of granisetron, a selective serotonin (5-HT3) receptor antagonist. It has a unique FDA indication for chemotherapy-induced nausea/vomiting (CINV) prophylaxis in patients receiving multi-day, moderately and/or highly emetogenic chemotherapy. The patch is applied to the upper outer arm 24-48 hours prior to chemotherapy and is kept on until at least 24 hours after chemotherapy is completed. The patch can be worn for up to 7 days, depending on chemotherapy regimen duration.

Definitions

"5-HT3 Receptor Antagonist" is a class of antiemetic agents (e.g. ondansetron, granisetron) that block serotonin binding to 5-HT3 receptors in the gut and central nervous system.

"Chemotherapy-Induced Nausea and Vomiting (CINV)" is nausea and/or vomiting that occurs as a side effect of chemotherapy treatment. It can be acute (within 24 hours of treatment) or delayed (more than 24 hours after treatment).

"Emetogenic Chemotherapy" is chemotherapy that has a high risk of causing nausea and vomiting.

"Moderately or Highly emetogenic chemotherapy" is chemotherapy that has >30%-90% or >90% frequency of nausea and/or vomiting, respectively (i.e., cisplatin, doxorubicin, carboplatinoxaliplatin, irinotecan, and azacitidine).

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Sancuso (granisetron) patch medically necessary when ALL of the following criteria are met:

1. The member is 18 years or older; *AND*

2. The member is receiving moderately or highly emetogenic chemotherapy for 2 days or more (see Appendix A, Table 1); *AND*
3. The member meets ONE (1) of the following[s]:
    a. Sancuso is being used to treat stage IV advanced, metastatic cancer [based upon applicable state regulations; *or*
    b. The member is unable to use, or has tried and failed at least ONE (1) oral 5-HT3 antagonist (e.g., granisetron, or ondansetron formulary alternatives); *or*
    c. The member is unable to swallow tablets or solutions.

<u>If the above prior authorization criteria are met, Sancuso (granisetron) patch will be approved for the duration of the chemotherapy regimen.</u>[s]

Experimental or Investigational or Unproven / Not Medically Necessary[s]

Sancuso (granisetron) patch for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary.

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Appendix A

Table 1[*]: Emetogenic Potential of Anticancer Agents and Recommended Preventive Antiemetic Regimens

Emetogenic Potential	Parenteral Agents	Oral Agents	Recommended Preventive Antiemetic Regimen
Highly Emetogenic (Frequency of Emesis: >90%)	❖ Anthracycline + cyclophosphamide (e.g., AC) ❖ Carboplatin Area Under the Curve (AUC) ≥4 ❖ Carmustine ❖ Chlormethine (Mechlorethamine) ❖ Cisplatin ❖ Cyclophosphamide ≥ 1,500 mg/m^2 ❖ Dacarbazine ❖ Datopotamab deruxtecan-dlkn ❖ Doxorubicin ≥ 60 mg/m^2 ❖ Epirubicin >90 mg/m^2 ❖ Fam-trastuzumab deruxtecan-nxki ❖ Ifosfamide ≥ 2g/m^2 per dose ❖ Melphalan ≥ 140 mg/m^2	❖ Abemaciclib ❖ Adagrasib ❖ Altretamine ❖ Avapritinib ❖ AzaCITIDine ❖ Binimetinib ❖ Bosutinib > 400 mg/day ❖ Busulfan ≥4 mg/day ❖ Cabozantinib ❖ Ceritinib ❖ Crizotinib ❖ Cyclophosphamide ❖ Dabrafenib ❖ Elacestrant ❖ Enasidenib ❖ Encorafenib ❖ Estramustine ❖ Etoposide ❖ Fedratinib	NK1 antagonist + 5HT3 antagonist + olanzapine + dexamethasone

Emetogenic Potential	Parenteral Agents	Oral Agents	Recommended Preventive Antiemetic Regimen
	❖ Sacituzumab govitecan-hziy ❖ Streptozocin ❖ Zolbetuximab-clzb	❖ Hexamethylmelamine ❖ Imatinib > 400 mg/day ❖ Lenvatinib > 12 mg/day ❖ Lomustine ❖ Midostaurin ❖ Mitotane ❖ Mobocertinib ❖ Niraparib ❖ Olaparib ❖ Procarbazine ❖ Ribociclib ❖ Rucaparib ❖ Selinexor ❖ Temozolomide ❖ Trifluridine and tipiracil ❖ Vinorelbine	
Moderately Emetogenic (Frequency of Emesis: 30% to 90%)	❖ Aldesleukin >12-15 million IU/m^2 or 600,000 IU/kg ❖ Amifostine > 300 mg/m^2 ❖ Azacitidine ❖ Bendamustine ❖ Busulfan ❖ Carboplatin AUC <4 ❖ Carmustine ≤ 250 mg/m^2 ❖ Clofarabine ❖ Cyclophosphamide < 1,500 mg/m^2 ❖ Cytarabine > 200 mg/m^2 ❖ Cytarabine/daunorubicin liposomal ❖ Dactinomycin ❖ Daunorubicin ❖ Dinutuximab beta ❖ Doxorubicin ❖ Epirubicin ≤ 90 mg/m^2 ❖ Idarubicin ❖ Ifosfamide 2g/m^2 per dose ❖ Irinotecan ❖ Irinotecan peg-liposomal ❖ Lubrinectedin ❖ Melphalan <140 mg/m^2 ❖ Methotrexate ≥ 250 mg/m^2 ❖ Mirvetuximab soravtansine-gynx ❖ Naxitamab ❖ Oxaliplatin ❖ Romidepsin ❖ Sactizumab-govitecan ❖ Temozolomide ❖ Thiotepa ❖ Trabectedin ❖ Tastuzumab-deruxtecan		NK1 antagonist + 5HT3 antagonist + dexamethasone
Low	❖ Ado-trastuzumab	❖ Abiraterone	5HT3 antagonist

Emetogenic Potential	Parenteral Agents	Oral Agents	Recommended Preventive Antiemetic Regimen
Emetogenic (Frequency of Emesis: 10% to 30%)	emtansine ❖ Aflibercept ❖ Aldesleukin ≤12 million IU/m^2 ❖ Amivantamab ❖ Arsenic trioxide ❖ Axicabtagene-ciloleucel ❖ Belinostat ❖ Blinatumomab ❖ Bortezomib ❖ Brentuximab-vedotin ❖ Cabazitaxel ❖ Carfilzomib ❖ Catumaxomab ❖ Cetuximab ❖ Ciltacabtagene autoleucel ❖ Copanlisib ❖ Cytarabine 100- 200 mg/m^2 ❖ Decitabine ❖ Docetaxel ❖ Doxorubicin peg-liposomal ❖ Elotuzumab ❖ Elranatamab-bcmm ❖ Enfortumab-vedotin ❖ Epcoritamab-bysp ❖ Eribulin ❖ Etoposide ❖ Floxuridine ❖ 5-Fluorouracil ❖ Gemcitabine ❖ Gemtuzumab-ozogamicin ❖ Idecabtagene vicleucel ❖ Inotuzumab-ozogamicin ❖ Isatuximab ❖ Ixabepilone ❖ Lifileucel ❖ Loncastuximab-tesirine ❖ Melphalan-flufenamide ❖ Methotrexate > 50 mg/m^2 to < 250 mg/m^2 ❖ Mirvetuximab-soravtansine ❖ Mitomycin ❖ Mitomycin pyelocalyceal	❖ Acalabrutinib ❖ Afatinib ❖ Alectinib ❖ Alpelisib ❖ Anastrozole ❖ Apalutamide ❖ Asciminib ❖ Axitinib ❖ Belzutifan ❖ Bexarotene ❖ Bicalutamide ❖ Brigatinib ❖ Busulfan <4 mg/day ❖ Capecitabine ❖ Capivasertib ❖ Capmatinib ❖ Chlorambucil ❖ Cobimetinib ❖ Cyclophosphamide < 100 mg/m^2/day ❖ Dabrafenib ❖ Dacomitinib ❖ Darolutamide ❖ Dasatinib ❖ Decitabine and cedazuridine ❖ Duvelisib ❖ Eflornithine ❖ Entrectinib ❖ Enzalutamide ❖ Erdafitinib ❖ Erlotinib ❖ Everolimus ❖ Exemestane ❖ Fludarabine ❖ Flutamide ❖ Futibatinib ❖ Gefitinib ❖ Gilteritinib ❖ Glasdegib ❖ Hydroxyurea ❖ Ibrutinib ❖ Idelalisib ❖ Imatinib ≤400 mg/day ❖ Infigratinib ❖ Ivosidenib	OR dexamethasone

Emetogenic Potential	Parenteral Agents	Oral Agents	Recommended Preventive Antiemetic Regimen
	solution ❖ Mitoxantrone ❖ Mogamulizumab-kpkc ❖ Mosunetuzumab-axgb ❖ Moxetumomab-pasudotox ❖ Necitumumab ❖ Nelarabine ❖ Omacetaxine ❖ Paclitaxel ❖ Paclitaxel nab-albumin ❖ Panitumumab ❖ Pemetrexed ❖ Pertuzumab ❖ Pentostatin ❖ Polatuzumab vedotin-piig ❖ Tafasitamab ❖ Tagraxofusp ❖ Talimogene laherparepvec ❖ Tebentafusp-tebn ❖ Teclistamab ❖ Thiotepa ❖ Tisagenlecleucel ❖ Tisotumab-vedotin ❖ Topotecan ❖ Trastuzumab-emtansine ❖ Ziv-aflibercept ❖ Vinflunine	❖ Ixazomib ❖ Lapatinib ❖ Larotrectinib ❖ Lenalidomide ❖ Letrozole ❖ Lorlatinib ❖ Megestrol ❖ Melphalan ❖ Mercaptopurine ❖ Methotrexate ❖ Momelotinib ❖ Neratinib ❖ Nilotinib ❖ Nilutamide ❖ Nirgacestat ❖ Nintedanib ❖ Niraparib/abiraterone acetate ❖ Olaparib ❖ Olutasidenib ❖ Osimertinib ❖ Pacritinib ❖ Palbociclib ❖ Panobinostat ❖ PAZOpanib ❖ Pemigatinib ❖ Pexidartinib ❖ Pirtobrutinib ❖ Pomalidomide ❖ PONATinib ❖ Pralsetinib ❖ Quizartinib ❖ Regorafenib ❖ Relugolix ❖ Repotrectinib ❖ Ribociclib ❖ Ripretinib ❖ Ruxolitinib ❖ Selpercatinib ❖ Sonidegib ❖ SORAfenib ❖ Sotorasib ❖ SUNItinib ❖ Talazoparib ❖ Tamoxifen ❖ Tazemetostat ❖ Tegafur/uraci ❖ Temozolomib ≤ 75	
Minimally Emetogenic (Frequency of Emesis: <10%)	❖ Alemtuzumab ❖ Asparaginase ❖ Atezolizumab ❖ Atezolizumab and hyaluronidase-tqjs ❖ Avelumab ❖ Belantamab-mafodotin ❖ Bevacizumab ❖ Bleomycin ❖ Blinatummomab ❖ Bortezomib ❖ Cemiplimab ❖ Cetuximab ❖ Cladribine ❖ Daratumumab ❖ Daratumumab and hyaluronidase-fihj		No routine prophylaxis

Emetogenic Potential	Parenteral Agents	Oral Agents	Recommended Preventive Antiemetic Regimen
	❖ Decitabine ❖ Degarelix ❖ Dexrazoxane ❖ Dostarlimab ❖ Durvalumab ❖ Elotuzumab ❖ Emapalumab ❖ Fludarabine ❖ Fulvestrant ❖ Glofitamab-gxbm ❖ Gosereline ❖ Histrelin ❖ Imetelstat ❖ Ipilmumab ❖ Lanreotide ❖ Leuprolide ❖ Lovotibeglogene autotemcel ❖ Luspatercept-aamt ❖ Margetuximab-cmkb ❖ Methotrexate ≤ 50 mg/m^2 ❖ Mosunetuzumab ❖ Nelarabine ❖ Nivolumab ❖ Nivollumab and hyaluronidase-nvhy ❖ Nivolumab/relatlimab=rmbw ❖ Obinutuzumab ❖ Ofatumumab ❖ Panitumumab ❖ Pembrolizumab ❖ Pertuzumab ❖ Pertuzumab/trastuzumab and hyaluronidase-zzxf ❖ Pixantrone ❖ Polatuzumab-vedotin ❖ Pralatrexate ❖ Ramucirumab ❖ Retifanlimab-dlwr ❖ Rituximab ❖ Rituximab and hyaluronidase ❖ Siltuximab ❖ Sirolimus-albumin ❖ Talquetamab-tgvs ❖ Tarlatamab-dlle	mg/m^2/day ❖ Tepotinib ❖ Thalidomide ❖ Tioguanin (6-Thioguanine) ❖ Tivozanib ❖ Topotecan ❖ Toremifene ❖ Trametinib ❖ Tretinoin ❖ Trifluridine/tipiracil ❖ Tucatinib ❖ Umbralisib ❖ Vandetanib ❖ Vemurafenib ❖ Venetoclax ❖ Vismodegib ❖ Vorinostat ❖ Zanubrutinib	

Emetogenic Potential	Parenteral Agents	Oral Agents	Recommended Preventive Antiemetic Regimen
	❖ Teclistamab-cqyv ❖ Temsirolimus ❖ Tislelizumab-jsgr ❖ Toripalimab-tpzi ❖ Trastuzumab ❖ Trastuzumab and hyaluronidase-oysk ❖ Tremelimumab ❖ Triptorelin ❖ Vinblastine ❖ Vincristine ❖ Vinorelbine		

NOTE: This table summarizes the emetogenic potential of parenteral and oral anticancer agents (not all-inclusive) and provides general recommended preventive antiemetic regimens based on guidelines. However, choice of antiemetic therapy should be individualized for each patient based on specific chemotherapy regimen, dosing, and risk factors. Higher doses of chemotherapy are generally more emetogenic. Patient factors like younger age, female gender, and prior CINV increase susceptibility. For combination regimens, the emetic level is based on the most emetic agent in the combination (except in the setting of anthracycline and cyclophosphamide, which are both moderate emetogenic agents but together are highly emetogenic).

Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 06/29/2023, 06/27/2024, 10/01/2025, 12/01/2025, 09/01/2026