Sancuso (granisetron) Patch

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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 multiday, 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

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

Medical Necessity Criteria for Authorization

The Plan considers Sancuso (granisetron) patch medically necessary when ALL of the following criteria is 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; *AND*
3. There is documentation, as applicable, and the member meets ONE of the following criteria:
    a. The member is unable to use, or has tried and failed at least ONE oral 5HT-3 antagonist such as granisetron tablet or ondansetron tablet; *or*
    b. The member is unable to swallow tablets or solutions;*or*
    c. Sancuso is being used to treat stage IV advanced, metastatic cancer [based upon applicable state regulations.

If the above prior authorization criteria are met, Sancuso (granisetron) patch will be approved for the duration of the chemotherapy regimen.

Experimental or Investigational / Not Medically Necessary

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

References

1. Armbruster SD, Fellman BM, Jhingran A, et al,. A phase III study of transdermal granisetron versus oral ondansetron for women with gynecologic cancers receiving pelvic chemoradiation. Support Care Cancer. 2021 Jan;29(1):213-222. doi: 10.1007/s00520-020-05484-z. Epub 2020 Apr 27.
2. Boccia RV, et al. Efficacy and tolerability of transdermal granisetron for the control of chemotherapy-induced nausea and vomiting associated with moderately and highly emetogenic multi-day chemotherapy: a randomized, double-blind, phase III study. Support Care Cancer. 2011;19(10):1609. Epub 2010 Sep 12.

3. Flank J, Robinson PD, Holdsworth M, et al. Guideline for the Treatment of Breakthrough and the Prevention of Refractory Chemotherapy-Induced Nausea and Vomiting in Children With Cancer. Pediatr Blood Cancer. 2016;63(7):1144-1151.[PubMed 26960036].
4. GA HB965 | 2023-2024 | Regular Session. Legiscan, https://legiscan.com/GA/research/HB965/2023. Accessed May 8, 2025
5. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: ASCO guideline update. J Clin Oncol. 2020;38(24):2782-2797. doi:10.1200/JCO.20.01296
6. Hesketh PJ. Prevention and Treatment of chemotherapy-induced nausea and vomiting in adults. https://www.uptodate.com/contents/prevention-and-treatment-of-chemotherapy-induced-nausea-and-vomiting-in-adults/print. Updated March 28, 2021. Accessed May 2, 2021.
7. IL HB4821 | 2023-2024 | 103rd General Assembly. Legiscan, https://legiscan.com/IL/bill/HB4821/2023. Accessed May 8, 2025.
8. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Antiemesis. National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Updated July 20, 2011. Accessed December 18, 2019.
9. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Antiemesis. National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf Updated March 27, 2025. Accessed April 11, 2025.
10. OH SB252 | 2019-2020 | 133rd General Assembly. Legiscan, https://legiscan.com/OH/bill/SB252/2019. Accessed May 8, 2025.
11. OK HB2748 | 2024 | Regular Session | Amended. Legiscan, https://legiscan.com/OK/text/HB2748/id/2859202. Accessed May 8, 2025.
12. PA HB427 | 2019-2020 | Regular Session | Amended. Legiscan, https://legiscan.com/PA/text/HB427/id/2069919. Accessed May 8, 2025.
13. Sancuso (granisetron transdermal) [prescribing information]. Bedminster, NJ: Kyowa Kirin; September 2024.
14. Schulmeister L. Granisetron transdermal system: a new option to help prevent chemotherapy-induced nausea and vomiting. Clin J Oncol Nurs. 2009;13(6):711-714. doi:10.1188/09.CJON.711-714.
15. TX HB1584 | 2019-2020 | 86th Legislature. Legiscan, https://legiscan.com/TX/bill/HB1584/2019. Accessed May 8, 2025.

Clinical Guideline Revision / History Information

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