Clinical Policy Title:	granisetron
Policy Number:	RxA.184
Drug(s) Applied:	granisetron Sancuso
Original Policy Date:	02/07/2020
Last Review Date:	12/05/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Nausea and Vomiting Associated with Cancer Chemotherapy (must meet all)**:**

1. Prescribed for the prevention or treatment of chemotherapy-induced nausea/vomiting;
2. Member is scheduled to receive moderately and/or highly emetogenic cancer chemotherapy;
3. Trial and failure of a 5-HT_3 receptor antagonist (e.g., ondansetron), unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Nausea and Vomiting Associated with Radiation Therapy (must meet all)**:**

1. Request is for granisetron tablet;
2. Prescribed for the prevention of radiation-induced nausea/vomiting;
3. Member is scheduled to receive radiation therapy;
4. Trial and failure of a 5-HT3 receptor antagonist (e.g., ondansetron) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Other Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.
2. Member meets one of the following (a or b):
   a. Member continues to receive cancer chemotherapy;
   b. Member continues to receive radiation therapy;

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Gan TJ, Diemunsch, P, Habib AS, et al, Society for Ambulatory Anesthesia Guidelines for the Management of Postoperative Nausea and Vomiting. Anesth Analg 2014; 118:85-113. Available at: https://pubmed.ncbi.nlm.nih.gov/24356162/. Accessed November 27, 2024.

2. Hesketh, PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol 2017: JCO2017744789. Available at: https://ascopubs.org/doi/10.1200/JCO.20.01296. Accessed November 27, 2024.
3. National Comprehensive Cancer Network. Antiemesis Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 27, 2024.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed November 27, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated: Kytril was removed due to drug discontinuation. 3. Line of Business Policy Applies to was updated to all lines of business. 4. Background was updated. 5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance...". 6. Dosing information updated to include oral and IV dose regimen for Nausea and Vomiting Associated with Cancer Chemotherapy and IV dose regimen for Postoperative Nausea/Vomiting, respectively. 7. Initial and Continued Approval Duration was updated to included Medicaid approval duration. 8. Initial approval duration for Postoperative Nausea/Vomiting was updated from one time (3 days) to one time (7 days). 9. Criteria I.C.f.i was updated from 1 mg to 3 mg. 10. APPENDIX B was updated: brand Zofran®ODT was removed due to drug discontinuation. 11. References were updated.	06/26/2020	09/14/2020
Policy was reviewed: 1. References were reviewed and updated. 2. Updated the language in I.A.3	02/22/2021	06/10/2021
Policy was reviewed: 1. Dosing Information, Dosing Regimen, Sustol®: Updated to include renal impairment dosing information for indication Prevention of nausea and vomiting associated with cancer chemotherapy. 2. Appendix B, Drug Name Updated to remove unavailable generic therapeutic alternative:	01/05/2022	04/18/2022

a. fosnetupitant chloride /palonosetron. b. netupitant/palonosetron. c. dolasetron. 3. Appendix B, Dosing Regimen was updated: a. Akynzeo®: Updated dosing information from 1 vial Intravenous given 30 min prior to chemotherapy on day 1 to 1 vial (fosnetupitant 235 mg; palonosetron 0.25 mg) Intravenous given 30 min prior to chemotherapy on day 1 for indication Prevention of nausea and vomiting associated with highly emetogenic chemotherapy. b. Akynzeo®: Updated dosing information from 1 capsule orally given 1 hour prior to initiation of chemotherapy on day 1 (in combination with dexamethasone) to 1 capsule (300 mg netupitant/0.5 mg palonosetron) orally given 1 hour prior to initiation of chemotherapy on day 1 (in combination with dexamethasone) 4. Appendix B, Maximum Dose was updated: a. Akynzeo® : Updated maximum dose information from 1 vial /chemotherapy cycle to 1 vial (fosnetupitant 235 mg; palonosetron 0.25 mg) /chemotherapy cycle for indication Prevention of nausea and vomiting associated with highly emetogenic chemotherapy. b. Akynzeo® : Updated maximum dose information from 1 capsule or vial/chemotherapy cycle to 1 capsule (300 mg netupitant/0.5 mg palonosetron) or vial/chemotherapy cycle for indication Prevention of nausea and vomiting associated with highly emetogenic chemotherapy. 5. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 6. Appendix C, Contraindications: Updated contraindication from Sancuso® is contraindicated in patients with known hypersensitivity to granisetron or to any of the components of the patch to Sancuso® is contraindicated in patients with known hypersensitivity to granisetron or to any of the transdermal system. 7. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 8. References were reviewed and updated.		

Policy was reviewed: 1. Background: Updated indication from Granisetron is a serotonin (5-HT3) receptor antagonist that is indicated for prevention of chemotherapy-associated nausea and vomiting. In addition, granisetron tablet is indicated for prophylaxis of radiation therapy-associated emesis to Granisetron is a serotonin (5-HT3) receptor antagonist that is indicated for prevention of chemotherapy-associated nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin. In addition, granisetron tablet is indicated for prophylaxis of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation. 2. Initial approval Criteria I.C: Updated to be removed as it was off-label indication and granisetron IV injection to not require prior authorization. 3. Initial approval criteria I.A.5 and I.B.5: Updated from formulary 5-HT_3 to trial and failure of 5-$HT_{3\ e.g.,}$ ondansetron. 4. Dosage Forms, granisetron hydrochloride intravenous: Updated dosage form from 4mg/4mL to 0.1 mg/mL. 5. Appendix B, Drug Name: Updated to remove generic therapeutic alternative dolasetron. 6. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative: a. Aloxi®; b. Zofran®. 7. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed. 1. Removed age criteria. 2. Removed dosing criteria for oral formulations. 3. Updated approval duration. 4. Removed reauthorization requirement for positive response to therapy.	12/22/2023	11/30/2023
Policy was reviewed: 1. Removed Sustol from policy 2. Added granisetron to policy	03/15/2024	02/28/2024
Policy was reviewed: 1. Removed documentation information. 2. Removed reference to Appendix D. 3. Removed dosing restriction. 4. Updated continued therapy approval criteria to 120 day lookback period. 5. Updated approval duration verbiage. 6. References were reviewed and updated.	9/4/2024	

Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..”	11/27/2024	12/05/2024