Clinical Policy: Granisetron (Sancuso)

Reference Number: PA.CP.PMN.74
Effective Date: 01/18
Last Review Date: 11/16
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Granisetron transdermal system (Sancuso®) is serotonin 5-hydroxytryptamine, type 3 (5-HT3) receptor antagonist.

FDA approved indication
- Prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria**

It is the policy of Pennsylvania Health and Wellness ® that Sancuso is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chemotherapy Induced Nausea and Vomiting (must meet all)**:**
1. Prescribed for the prevention of chemotherapy-induced nausea and vomiting;
2. Member is receiving chemotherapy for up to 5 consecutive days;
3. Failure of ondansetron trial at maximum indicated doses, unless member has contraindication(s) or intolerance to ondansetron;
4. Requested does not exceed 1 patch/week and health plan approved quantity limit.

Approval duration: projected course of chemotherapy up to 72 hours after completion of chemotherapy

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Chemotherapy Induced Nausea and Vomiting Prophylaxis (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation that member is currently receiving chemotherapy or will be receiving chemotherapy;
3. If request is for a dose increase, new dose does not exceed 1 patch/week and health plan approved daily quantity limit.

Approval duration: projected course of chemotherapy up to 72 hours after completion of chemotherapy

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: duration of request or 3 months (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
5-HT3: serotonin 5-hydroxytryptamine, type 3

V. Dosage and Administration

Drug	Recommended Dosage	Maximum Dose
Sancuso (granisetron)	Apply a single transdermal system (patch) 24 hours before chemotherapy. The patch can be worn for up to 7 days depending on the duration of the chemotherapy regimen.	1 patch; remove patch a minimum of 24 hours after completion of chemotherapy

VI. Product Availability

Transdermal system: 52 cm^2 patch containing 34.3 mg of granisetron delivering 3.1 mg per 24 hours

VII. References

1. Sancuso Prescribing Information. Bedminster, NJ: ProStakan, Inc., September 2015. Available at http://www.sancuso.com. Accessed August 24, 2016.
2. Clinical Pharmacology. Tampa, FL: Gold Standard; 2008. Available at www.clinicalpharmacology.com. Accessed August 24, 2016.
3. Basch E, Prestrud AA, Hesketh PJ et al. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2011 Nov 1;29(31):4189-98. doi: 10.1200/JCO.2010.34.4614. Epub 2011 Sep 26.

Reviews, Revisions, and Approvals	Date	Approval Date