Sancuso® (granisetron transdermal system) Step Therapy Criteria Program Summary

This program applies to Commercial, NetResults A series, NetResults F series, and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Sancuso (granisetron transdermal system) Step Therapy (ST) program is to encourage the use of cost-effective oral generic antiemetics over the more expensive brand Sancuso transdermal system. Prerequisite antiemetics include oral generic selective 5-HT3 (5-hydroxytryptamine-3) receptor antagonists - granisetron tablets, ondansetron tablets, ondansetron disintegrating tablets, and ondansetron solution; the generic ondansetron injection is not included in the program prerequisites. This step therapy program will accommodate for use of Sancuso when the prerequisite oral agents cannot be used due to previous trial, documented intolerance, FDA labeled contraindication, or hypersensitivity to the prerequisites. The program allows continuation of therapy when there is documentation that the patient is receiving the requested agent. Requests for Sancuso will be reviewed when patient-specific documentation has been provided.

TARGET DRUGS

Sancuso® (granisetron transdermal system)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Sancuso will be approved when ONE of the following is met:

1. The patient's medication history indicates previous use of generic oral granisetron or generic oral ondansetron
   OR
2. There is documentation that the patient is currently using the requested agent
   OR
3. The prescriber states the patient is currently using the requested agent AND is at risk if therapy is changed
   OR
4. The patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to generic oral granisetron or generic oral ondansetron products

Length of approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1]

Drug	FDA Indication(s)	Administration and Dosing
Sancuso granisetron 34.3 mg transdermal system (3.1 mg/24 hr)	For the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days	Apply a single patch a minimum of 24 hours before chemotherapy. Patch can be worn for up to 7 days and should be removed 24 hours after the end of chemotherapy

CLINICAL RATIONALE

The National Comprehensive Cancer Network (NCCN) guideline for the treatment of chemotherapy or radiotherapy induced nausea and vomiting does not distinguish between the oral and transdermal patch formulations of granisetron in its treatment algorithm placement. The guideline also does not recommend a preference between granisetron and ondansetron in its treatment algorithms.[2] The Multinational Association of Supportive Care in Cancer (MASCC)/European Society of Medical Oncology (ESMO) does not distinguish between 5-HT3 agents in its treatment algorithms.[4]

In a comparative clinical trial, the granisetron transdermal patch was shown to be non inferior to oral granisetron in the prevention of nausea and vomiting.[1] The granisetron transdermal patch must be applied 24-48 hours before the start of chemotherapy. Patients often have blood counts tested on the day of chemotherapy and if they do not qualify for chemotherapy that day, the patch may be wasted. The manufacturer of the granisetron patch does provide free replacement patches to patients that waste one.[1]

All of the 5HT-3 receptor antagonists can prolong the QT interval, although manufacturers recommend different levels of monitoring for each drug. Manufacturers of palonosetron and granisetron do not provide specific precautions or monitoring recommendations within the package labeling, while ondansetron and dolasetron manufacturers recommend caution and monitoring in patients with any condition or concomitant drug that can prolong the risk of QT interval prolongation. The manufacturer of dolasetron also recommends caution and monitoring in patients with any condition or concomitant drug that can prolong the PR or QRS intervals. Torsade de Pointe has been reported with dolasetron and ondansetron. In addition to dose dependent PR- and QRS-interval prolongation; dolasetron also causes second or third degree atrioventricular block, cardiac arrest, and serious ventricular arrhythmias (some fatal) have been reported in pediatrics and adults. ECG monitoring is recommended in select patient populations with increased risk who receive dolasetron or ondansetron.[3]

REFERENCES

1. Sancuso prescribing information. ProStrakan. September 2015.
2. National Comprehensive Cancer Network (NCCN). Antiemesis Guidelines in Oncology. Version 1.2016. Accessed 3/25/2016
3. Clinical Pharmacology. http://www.clinicalpharmacology-ip.com/Default.aspx. Accessed 3/3/2015.
4. 4 MASCC/ESMO Antiemetic guideline 2016. Accessed 4/22/2016 at: http://www.mascc.org/assets/Guidelines-Tools/mascc_antiemetic_guidelines_english_2016_v.1.1.pdf.