nh healthy families

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Antiemetics (5-HT3 Antagonists)
PAGE: 1 of 6	**REFERENCE NUMBER:** NH.PMN.11
EFFECTIVE DATE: 09/06	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED: 11/13**, 08/16, 07/17
PRODUCT TYPE: All	**REVISED:** 02/08, 05/08, 11/09, 10/10, 11/11, 11/12, 11/13, 12/14

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description: The 5-HT_3 antagonists are antinauseant and antiemetic agents that antagonize both central and peripheral 5-HT_3 receptors. Current evidence indicates that the 5-HT_3 receptors play an important role in the mechanism of acute emesis and are considered first line therapy for the use of moderate – severely emetogenic chemotherapy.

FDA Labeled Indications:

1. Chemotherapy induced nausea and vomiting.
2. Prevention and treatment of postoperative nausea and vomiting (ondansetron and Anzemet).
3. Radiation induced nausea and vomiting (ondansetron and Kytril only).

Criteria for Approval:

A. For chemotherapy induced nausea and vomiting, postoperative nausea and vomiting, and radiation induced

nausea, failure of, or intolerance to ondansetron; Sancuso may only be approved in patients receiving moderately or highly emetogenic chemotherapy planned for 5 or more consecutive days.

B.

Approval: *Chemo/Radiation Therapy*

Initial Approval: Duration to cover the projected course of chemo/radiation therapy. To include enough medication for the 72 hour time period after completing chemo/radiation therapy. For Sancuso, 1 patch for up to 7 total days. Continued Approval: Throughout the chemotherapy or radiation therapy regimen (cycles) if patient presents with ongoing nausea/vomiting.

Post-Operative Nausea

Initial Approval: For post-operative nausea, the prior authorization is for 72 hours.

Continued Approval: After 3 months, the quantity limit reverts back to 10 tablets per month, in the absence of a prior authorization request.

Special Instructions

> See prescribing information for appropriate dosing.
> 5-HT_3 antagonist are not considered first line therapy for delayed emesis.
> All of the 5-HT_3 antagonists and metoclopramide are Pregnancy Category B; prochlorperazine (Compazine®) and promethazine (Phenergan®) are Pregnancy Category C.
> Anzemet prolongs the QT interval in a dose dependent fashion. Avoid Anzemet in patients with congenital long QT syndrome, hypomagnesemia, or hypokalemia.

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References: 1. Prevention and Treatment of Postoperative Nausea and Vomiting. *American Journal of Health-System Pharmacy*. 2005;62(12):1247-1260. Accessed on Medscape. http://www.medscape.com/viewarticle/506997

2. Guidelines for Antiemetic Treatment of Chemotherapy-Induced Nausea and Vomiting: Past, Present, and Future Recommendations. *The Oncologist*, Vol. 12, No. 9, 1143-1150, September 2007; doi:10.1634/theoncologist.12-9-1143. http://theoncologist.alphamedpress.org/cgi/content/full/12/9/1143
3. American Academy of Family Physicians, Nausea and Vomiting of Pregnancy, *Am Fam Physician.* Jul 1;68(1):121-128, July 2003. http://www.aafp.org/afp/20030701/121.html
4. American Society of Clinical Oncology Guideline for Antiemetics in Oncology: Update 2006. *Journal of Clinical Oncology*, Vol 24, No 18 (June 20), 2006: pp. 2932-2947. DOI: 10.1200/JCO.2006.06.9591 http://jco.ascopubs.org/content/24/18/2932.full
5. Kytril/Granisol/Sancuso drug monograph. Clinical Pharmacology. Accessed October 2014.
6. Anzemet drug monograph. Clinical Pharmacology. Accessed October 2014.

Revision Log	
Revision	**Date**
Remove the following from the "Brand" section: "ondansetron (Zofran®) – 4mg, 8mg, 24mg, tablets, 4mg/5mL solution" and "ondansetron (Zofran ODT®) – 4mg, 8mg disintegrating tablets".	02/08

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Change "Criteria for Approval" item "a." from "failure of, or intolerance to, two formulary antiemetics (prochlorperazine, metoclopramide, promethazine, dexamethasone, lorazepam); or" to "For chemotherapy, postoperative nausea and vomiting, and radiation induced nausea, failure of, or intolerance to, two formulary antiemetics (prochlorperazine, metoclopramide, promethazine, dexamethasone, ondansetron); or".	02/08
Add the following to "Criteria for Approval" item "b." "who have failed an ondansetron trial"	02/08
Change "Criteria for Approval" item "a." from "For pregnant patients with hyperemesis gravidarum non-responsive to pyridoxine, ranitidine metoclopramide, all of the 5-HT_3 antagonists and metoclopramide are pregnancy category B; prochlorperazine (Compazine®) and promethazine (Phenergan®) are category C. Requests for 5-HT_3 antagonists in pregnant women should be reviewed on an individual basis. If the patient is unable to use ranitidine or metoclopramide then a reasonable contraindication should be documented." to "For pregnant patients with hyperemesis gravidarum non-responsive to pyridoxine in combination with meclizine, dimenhydrinate or diphenhydramine, metoclopramide, or promethazine, extended ondansetron therapy can be considered as a treatment option and the quantity limit can be adjusted accordingly. Initial dosing of ondansetron 4mg twice a day should be trialed before titration up. All of the 5-HT_3 antagonists and metoclopramide are pregnancy category B; prochlorperazine (Compazine®) and promethazine (Phenergan®) are category C. Requests for 5-HT_3 antagonists in pregnant women should be reviewed on an individual basis. If the patient is unable to use pyridoxine, antihistamines, metoclopramide or promethazine, then a contraindication should be documented."	02/08
Add the following to "Approval": with extensions of up to a month supply considered for patients with severe symptoms or who have	02/08

required prior rehydration therapy.	
Change "trialed" to "tried" in the "Criteria for Approval" section item "c"	05/08
Removed the following from the "Criteria for Approval" section: "All of the 5-HT3 antagonists and metoclopramide are pregnancy category B; prochlorperazine (Compazine®) and promethazine (Phenergan®) are category C. Requests for 5-HT3 antagonists in pregnant women should be reviewed on an individual basis. If the patient is unable to use pyridoxine, antihistamines, metoclopramide or promethazine, then a contraindication should be documented."	11/09
Added the following to "Criteria for Approval" item "c.", "Ondansetron is not subject to prior authorization (see limitations below)."	11/09
Revised the "Approval" section for diagnosis of hyperemesis gravidarum from "For the diagnosis of hyperemesis gravidarum is a 14 day supply, with extensions of up to a month supply considered for patients with severe symptoms or who have required prior rehydration therapy" to "For the diagnosis of hyperemesis gravidarum., ondansetron is the preferred drug in this category. A quantity limit of 2 tablets per day, of either strength, has been programmed for a period of 3 months. After 3 months, the quantity limit reverts back to 10 tablets per month, in the absence of a prior authorization request."	11/09
Added the following to the "Special Instructions" section: "All of the 5-HT3 antagonists and metoclopramide are Pregnancy Category B; prochlorperazine (Compazine®) and promethazine (Phenergan®) are Pregnancy Category C."	11/09
Removal of requirement for **two** PDL antiemetics and requiring only a failure of ondansetron.	10/10
Continued approval updated to include coverage throughout chemo/radiation therapy cycles, if needed.	10/10
References updated.	10/10

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References updated.	11/11
Add the following to "Brand" "granisetron (Granisol): 2mg/10ml oral solution and granisetron (Sancuso): 3.1mg/24 hr transdermal patch"	11/12
Add the following to "Criteria for Approval:" item "A." "Sancuso may only be approved in patients receiving moderately or highly emetogenic chemotherapy planned for 5 or more consecutive days."	11/12
Add the following to "Approval: Chemo/Radiation Therapy" "For Sancuso, 1 patch for up to 7 total days."	11/12
References updated.	11/12
Added that "Anzemet prolongs the QT interval in a dose dependent fashion. Avoid Anzemet in patients with congenital long QT syndrome, hypomagnesemia, or hypokalemia" to special instruction section.	11/13
References updated.	11/13
References updated. Removed ondansetron from policy since it is a preferred agent.	
Removed oral from title.	06/15
Removed reference to any brand name drugs.	06/15
Annual Review, No changes	08/16
Annual Review, No Changes	07/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file