JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS056
		Effective Date	04/01/2009
		Review Date	12/21/2015
	Subject **Antiemetics: Non-formulary and Quantity Limit Exceptions (Emend, Anzemet, Sancuso, dronabinol, ondansetron, granisetron, Varubi)**	*Revision Date*	01/20/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: antiemetics

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I. POLICY

A. Oral and injectable antiemetic agents that are non-formulary, or prescribed in quantities that exceed the Plan limits, will require prior authorization for outpatient prescription drug benefit coverage. The process for initiating a prior authorization request can be found in policy PHARM 20. Non-formulary agents must first be reviewed for coverage as described in policy PHARM16, before quantity limit exceptions above FDA-guidance are considered.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Non-Formulary Antiemetic Exception**:
   1. Non-formulary antiemetics may be approved for patients meeting the following:
      a. Documentation has been provided showing trial and failure of at least 2 formulary antiemetics for a clinically appropriate indication
   2. Varubi-specific criteria:
      a. Documentation has been provided showing trial and failure of formulary generic aprepitant (Emend) for a clinically appropriate indication

B. **Quantity Limit Exception:**
   1. **5-HT3 Receptor Antagonists**
      a. Quantities of 5-HT3 receptor antagonists (dolasetron, granisetron, ondansetron, or palnosetron) exceeding the MDL, or FDA-approved dosing, may be approved in the following circumstances:
         i. The patient is undergoing more than one course of chemotherapy and/or radiation per month.
         ii. The patient is using an antiemetic for postoperative nausea and vomiting, and is undergoing more than one operative procedure in the month.

b. **Ondansetron in Pregnancy**: Higher quantities of ondansetron may be approved for pregnant patients in the following circumstances:
   i. The patient is diagnosed with hyperemesis gravidarium and meets all the following criteria:
      a. Persistent vomiting despite nonpharmacologic therapy and therapy with ≥ 2 pregnancy category B antiemetics (dimenhydramine, diphenhydramine, meclizine, and metoclopramide).
      b. Maternal fluid status is compromised.
      c. Maternal weight is decreased or remains unchanged from pre-pregnancy.
   ii. The patient is diagnosed with hyperemesis gravidarium and is being transitioned from IV antiemetics received during a hospital inpatient stay.

c. **Miscellanous Antiemetics**: More frequent use of formulary, or approved non-formulary antiemetics may be approved for patients undergoing more than one course of chemotherapy and/or radiation per month.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 3 months of therapy
B. Approval for continuation of therapy may be extended in six-month intervals.

IV. EXCLUSIONS

A. Higher doses of antiemetic agents are not approved for members who do not meet the criteria outlined above.
B. Antiemetic agents will not be approved for indications and usages that are not FDA-approved or guideline-supported
C. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

Generic name	Brand name	Recommended Dose
aprepitant	Emend	**Chemotherapy**: 125 mg orally one hour prior to chemotherapy, followed by 80 mg daily for the next 2 days
dolasetron	Anzemet	**Chemotherapy**: 100 mg orally, 100 mg IV, or 1.8 mg/kg IV one hour prior to chemotherapy; **PONV**: 2.5 mg IV at onset of nausea and vomiting or (for prophylaxis) 100 mg orally within 2 hours prior to surgery or 12.5 mg IV 15 min prior to cessation of anesthesia
dronabinol	Marinol	**Chemotherapy**: 5 mg/m^2 orally 1-3 hours prior to chemotherapy, followed by repeat doses up to 4-6 doses per day; **HIV-associated anorexia**: 2.5 – 10 mg orally twice daily
granisetron	Kytril	**Chemotherapy**: 10 mcg/kg IV 30 min prior to chemotherapy or 2 mg orally one hour prior to chemotherapy or 1 mg orally one hour prior to chemotherapy and 1 mg orally 12 hours later *or* one patch applied up to 48 hours prior to chemotherapy to remain in place for up to 7 days **Radiation**: 2 mg orally one hour prior to radiation; **PONV**: 1 mg IV prior to induction or immediately before reversal of anesthesia
nabilone	Cesamet	**Chemotherapy**: 1 – 2 mg orally twice daily

ondansetron	Zofran	**Chemotherapy**: 4 – 8 mg orally or 0.15 mg/kg or 32 mg IV 30 min prior to moderately ematogenic therapy with repeat doses every 12 hours for 1-2 days or 24 mg 30 min prior to highly ematogenic therapy; **Radiation**: 8 mg orally three times daily for 1-2 days; **PONV**: 4 mg IV or IM or 0.1 mg/kg IV immediately prior to induction of anesthesia
rolapitant	Varubi	**Chemotherapy:** 180mg orally 1-2 hours prior to start of treatment

VI. AFFECTED PRODUCTS

Generic name	Brand name	Limit per 30 days
aprepitant capsules	Emend	9
dolasetron tablets	Anzemet	3
dolasetron injection	Anzemet	1.875 mL (3 single-use vials)
dronabinol capsules	Marinol	60
granisetron oral solution	Kytril & generic	30 mL
granisetron tablets	Kytril & generic	6
granisetron injection	Kytril	6 mL (6 single-use vials)
granisetron patch	Sancuso	2
nabilone	Cesamet	24
ondansetron tablets and ODTs	Zofran & generic	90
ondansetron oral solution	Zofran	180 mL
rolapitant	Varubi	2

VII. REFERENCES

1. Nolte MJ, Berkery R, Pizzo B et al. Assuring the optimal use of serotonin antagonist antiemetics: the process for development and implementation of institutional antiemetic guidelines at Memorial Sloan-Kettering Cancer Center. *J Clin Oncol* 1998; 16: 771
2. American College of Obstetrics and Gynecology. ACOG Practice Bulletin No. 52: Nausea and Vomiting of Pregnancy. *Obstet Gynecol* 2004; 103: 803-15.
3. Sancuso Prescribing Information. Strakan Pharmaceuticals. September 12, 2008.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE

JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS056
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04/20/2016	Removed background information, removed process of initiation of request
07/27/2017	Exclusions section updated regarding physician samples
06/14/2018	Revised layout and clarified existing criteria
07/01/2018	Removed EHP Line of Business
05/09/2019	Removed Aloxi capsules as applicable product (discontinued by manufacturer); Clarified coverage criteria for Varubi
01/20/2021	Revised quantity limit references for ondansetron

Review/Revision Dates: 1/13/09, 4/1/09, 3/1/14, 12/21/2015, 4/20/2016, 7/27/2017, 06/14/2018, 07/01/2018, 05/09/2019, 01/20/2021