Antiemetic Agents Step Therapy with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

FDA APPROVED INDICATIONS[1-8]

Agent(s)	Indication(s)
Akynzeo® (netupitant/palonosetron) Capsule	• In combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy
Anzemet® (dolasetron) Tablet	• Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years of age and older

Emend® (aprepitant)
 	
Capsule[a]
Oral suspension
	Emend capsules
	• In combination with other antiemetic agents, in patients 12 years of age and older for the prevention of:
	  • Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy (HEC) including high-dose cisplatin
	  • Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)
	
	Emend oral suspension
	• In combination with other antiemetic agents, in patients 6 months of age and older for the prevention of:
	  ○ Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin
	  ○ Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)
	
	Limitations of use:
	• Emend has not been studied for treatment of established nausea and vomiting
	• Chronic continuous administration of Emend is not recommended

Agent(s)	Indication(s)
Granisetron[b] Tablet	• Prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high dose cisplatin • Prevention of nausea and/or vomiting associated with radiotherapy
ondansetron[b] Tablet Oral disintegrating tablet Oral solution	• Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m^2 • Prevention of nausea and/or vomiting associated with initial and repeat courses of moderately emetogenic cancer therapy • Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen • Prevention of postoperative nausea and/or vomiting
Sancuso® (granisetron) Transdermal patch	• Prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days
Varubi® (rolapitant) Tablet	• Used in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy
Zuplenz® (ondansetron) Oral soluble film	Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m^2 • Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy in adults and pediatric patients 4 years of age and older • Prevention of nausea and vomiting associated with radiotherapy in adult patients receiving either total body irradiation, single high-dose fraction to abdomen, or daily fractions to abdomen • Prevention of postoperative nausea and/or vomiting

a – generics available
b – available as generic only

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Guidelines

Multiple randomized clinical trials along with current guidelines in antiemesis demonstrate that granisetron (oral and injectable), ondansetron (oral and injectable), palonosetron (injectable), and dolasetron (oral) are largely therapeutically equivalent and considered first line treatment

for chemotherapy induced nausea and vomiting (CINV), radiation induced nausea and vomiting (RINV) and postoperative nausea and vomiting (PONV) and are associated with relatively few mild adverse events.[9-11]

Chemotherapy and Radiation Therapy Induced Nausea and Vomiting
Nausea and vomiting caused by anticancer agents and/or radiation therapy (RT) can have significant impact on a patient's quality of life, leading to poor compliance with further anticancer agents and/or RT. In addition, nausea and/or vomiting can result in dehydration, metabolic imbalances, degeneration of self-care and functional ability, nutrient depletion, anorexia, decline of the patient's performance status and mental status, wound dehiscence, esophageal tears, and withdrawal from potentially useful or curative anticancer treatment.[9]

The incidence and severity of nausea and/or vomiting in patients receiving anticancer agents and/or RT are affected by several factors including specific chemotherapy agents, dose, route of administration, schedule of administration, radiation target, and patient variability (age, sex, prior chemotherapy, history of alcohol use, etc.). In highly emetogenic regimens more than 90% of patients will experience episodes of vomiting but only about 30% will do so when given antiemetic prophylactic therapy.[10]

Vomiting is triggered by afferent impulses to the vomiting center from the chemoreceptor trigger zone, pharynx and gastrointestinal tract (GI), and cerebral cortex. The principal chemoreceptors involved in the emetic response are the serotonin and dopamine receptors. Additional neuroreceptors stimulated include acetylcholine, corticosteroid, histamine, cannabinoid, opioid, and neurokinin-1 receptors. Due to the variety of receptors involved and no final common pathway for emesis identified, multiple agents are used to block different pathways to provide a synergistic effect in an antiemesis prophylactic regimen.[10]

There are several identified classes of CINV including acute onset (typically occurs within the first few minutes to hours after chemotherapy administration), delayed onset (occurs more than 24 hours after chemotherapy dosing), anticipatory (occurs prior to chemotherapy administration and is considered a conditioned response), breakthrough (occurs despite prophylactic treatment and requires "rescue" antiemetic agents), and refractory (occurs during subsequent chemotherapy treatment cycles despite prophylactic and rescue therapy).[10]

National Comprehensive Cancer Network (NCCN) Guidelines recommend antiemetic therapy begins prior to chemotherapy and continues for the same length of time as the duration of the emetic activity of the drug given. The frequency of chemotherapy induced emesis depends mostly on the potential for the regimen to cause nausea and vomiting. Many chemotherapy regimens have been categorized by their potential to cause emesis. The classification (i.e., high, moderate, low, minimal) is based on the percentage of patients that experience acute emesis. High emetogenic risk is defined as 90% or more of patients, moderate risk has 30%-90% of patients, low risk is between 10% and 30% of patients, and minimal risk is <10% of patients experience acute emesis.[10]

The American Society of Clinical Oncology (ASCO) Practice Guidelines for Antiemetics in Oncology recommends that for patients who receive high-risk radiation therapy, patients receive a 5-HT3 antagonist before each radiation fraction and at least 24 hours after completing radiation therapy. Patients should also be given a five-day course of dexamethasone during fractions one to five.[9]

NCCN recommends starting pretreatment for each day of radiation therapy treatment with either granisetron or ondansetron, with or without dexamethasone.[10]

NCCN suggests when a serotonin (5-HT3) antagonist is used as part of an antiemetic regimen that does not include an NK-1 antagonist, either palonosetron or granisetron extended-release

injection is the preferred 5-HT3 antagonist compared to the other 5-HT3 antagonists [i.e., ondansetron, granisetron (tablets, intravenous injection), dolasetron], due to longer half-life and prolonged inhibition of the 5-HT3 receptor.[10]

NCCN and ASCO recommend the following for CINV and RINV:[9-10]

Emetic Risk	Antiemetic Therapy
IV Chemotherapy Acute and Delayed Emesis Prevention	
High Emetic Risk	olanzapine + NK-1RA + 5-HT3 + DEX (preferred)
	olanzapine + palonosetron IV +DEX
	NK-1RA + 5-HT3 + DEX
Moderate Emetic Risk	5-HT3 + DEX
	NK-1RA + 5-HT3 + DEX
	olanzapine + palonosetron IV +DEX
Low Emetic Risk	DEX
	metoclopramide
	prochlorperazine
	5-HT3 (excluding palonosetron IV)
Minimal Emetic Risk	No routine prophylaxis
Oral Chemotherapy Acute and Delayed Emesis Prevention	
High to Moderate Emetic Risk	Oral 5-HT3
Low to Minimal Emetic Risk (PRN recommended)	Oral 5-HT3
	metoclopramide
	prochlorperazine
Breakthrough Treatment	
Breakthrough Treatment	olanzapine (atypical antipsychotic) (preferred)
Add one agent from a different drug class to the current regimen	dolasetron, granisetron, ondansetron (5-HT3)
	lorazepam (benzodiazepine)
	dronabinol, nabilone (cannabinoid)
	DEX (steroid)
	prochlorperazine, promethazine (phenothiazine)
	haloperidol, metoclopramide, scopolamine patch (other)
Radiation-induced	
Radiation therapy – upper abdomen/localized sites	Oral granisetron ± DEX
	Oral ondansetron ± DEX
Total body irradiation	Oral granisetron ± DEX
	Oral ondansetron ± DEX
Chemotherapy and radiation therapy	See emesis prevention for chemotherapy-induced nausea/vomiting
Pediatric patients	
High emetic risk	5-HT3 + DEX + aprepitant
	5-HT3 + DEX + fosaprepitant
	5-HT3 + DEX
	palonosetron + aprepitant
	palonosetron + fosaprepitant
Moderate emetic risk	5-HT3 +DEX
	5-HT3 +aprepitant
	5HT-3 + fosaprepitant
Low emetic risk	ondansetron
	granisetron

Emetic Risk	Antiemetic Therapy
Minimal emetic risk	Should not be offered routine antiemetic prophylaxis

NK-1RA (aprepitant, fosaprepitant, netupitant, rolapitant) = neurokinin 1 antagonist; 5-HT3 = Serotonin 5-HT3 antagonist (dolasetron, granisetron, ondansetron, palonosetron IV); DEX = dexamethasone

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.[4] 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.[5]

Postoperative Nausea and Vomiting

Nausea and vomiting are two of the most common adverse events in the postoperative period with an estimated incidence of 30% in the general surgical population and as high as 80% in high risk patients. Unresolved postoperative nausea and vomiting (PONV) is a highly distressing experience and may result in prolonged post anesthesia care unit stay and unanticipated hospital admission that leads to a significant increase in overall health care costs. The goal of PONV prophylaxis is to decrease the incidence of PONV, patient-related distress, and health-care costs.[11]

Optimal management of PONV is a complex process. There are numerous antiemetics with varying pharmacokinetics, efficacy, and side-effect profiles, thus the choice of an antiemetic will depend on the clinical context. The benefit of PONV prophylaxis also needs to be balanced with the risk of adverse effects. At an institutional level, the management of PONV is also influenced by factors such as cost-effectiveness, drug availability, and drug formulary decisions.[11]

The Society for Ambulatory Anesthesiology has published Consensus Guidelines for the management of postoperative nausea and vomiting. The goals of these guidelines include:[12]

- Identification of reliable predictors of PONV risks in adults and postoperative vomiting in children
- Establishment of interventions which reduce baseline risks for PONV
- Identify the most effective antiemetic single therapy and combination therapy regimens for PONV prophylaxis
- Evaluation of the efficacy of PONV and post-discharge nausea and vomiting (PDNV) treatment with or without prior PONV prophylaxis
- Determination of the optimal dosing and timing of antiemetic prophylaxis
- Appraisal of the cost-effectiveness of PONV management strategies
- Creating an algorithm to summarize the risk stratification, risk reduction, prophylaxis, and treatment of PONV
- Evaluating the management of PONV recovery pathways
- Proposal of a research agenda for future studies

Risk for PONV in adults can be identified using an assessment called Apfel's simplified risk score for identification of high-risk patients.[11,13] Patients are given 1 point for each of the following when met:

- Female gender
- Non-smoker
- History of PONV and/or motion sickness
- Postoperative opioids

A score of 0, 1, 2, 3, and 4 correlates with an approximate risk of PONV of 10%, 20%, 40%, 60% and 80% respectively. Patients with a score of 0-1 are classified as low risk, a score of 2 is medium risk, and a score of 3-4 indicates high risk.[11,13]

Risk for PDNV in adults can also be assessed using an assessment also by Apfel et al. Patients are given 1 point for each of the following when met:[11,13]

- Female gender
- History of PONV
- Age < 50
- Use of opioids in postanesthesia care unit (PACU)
- Nausea in PACU

A score of 0, 1, 2, 3, 4, or 5 correlates with an approximate risk of PDNV of 10%, 20%, 30%, 50%, 60%, and 80% respectively.[11,13]

The risk factors for POV/PONV in children are different from those in adults. Pediatric patients are evaluated using a Simplified Risk Score from Eberhart et al.[11,14] Similar to the adult risk factor assessments, patients are given 1 point for each risk factor met.

- Surgery ≥ 30 minutes
- Age ≥ 3 years
- Strabismus surgery
- History of POV or family history of PONV

A score of 0, 1, 2, 3, or 4 correlates with an approximate risk of POV of 10%, 10%, 30%, 50%, and 70% respectively.[11,14]

The guidelines recommend the use of multimodal prophylaxis in patients with one or more risk factors for PONV. Patients with 1-2 risk factors for PONV should receive 2 agents for prophylaxis of PONV and patients with > 2 risk factors should receive 3-4 agents for prophylaxis. Ondansetron is the most commonly used and studied 5-HT_3 receptor antagonist and is considered the gold standard in PONV management.[11]

There is not sufficient evidence for the guidelines to guide the clinician to select the most effective individual antiemetic over other combination therapies with the exception of using agents from a different pharmacologic class. Recommended agents for adults and children (listed in alphabetical order) are: Note not all products are available in the United States and not all products are FDA labeled for PONV.[11]

Adults

- Amisulpride (IV)
- Aprepitant (oral)
- Casopitant (oral)
- Dexamethasone (IV)
- Dimenhydrinate (IV)
- Dolasetron (IV)
- Droperidol (IV)
- Ephedrine (IM)
- Granisetron (IV)
- Haloperidol (IM/IV)
- Methylprednisolone (IV)
- Metoclopramide (oral)
- Ondansetron (IV or oral disintegrating tablet)
- Palonosetron (IV)
- Perphenazine (IV)
- Promethazine (oral)

- Ramosetron (IV)
- Rolapitant (oral)
- Scopolamine (transdermal patch)
- Tropisetron (IV)

Pediatrics
- Aprepitant (IV)
- Dexamethasone (IV)
- Dimenhydrinate (IV)
- Dolasetron (IV)
- Droperidol (IV)
- Granisetron (IV)
- Ondansetron (IV)
- Palonosetron (IV)
- Tropisetron (IV)

Nausea and Vomiting of Pregnancy[12]
American College of Obstetricians and Gynecologists (ACOG, 2015) recommends the following for nausea and vomiting during pregnancy:
- Taking prenatal vitamins for 3 months before conception may reduce the incidence and severity of nausea and vomiting of pregnancy
- Treatment of nausea and vomiting of pregnancy with vitamin B6 or vitamin B6 plus doxylamine is safe and effective and should be considered first-line pharmacotherapy. Medications for which there are some safety data but no conclusive evidence of efficacy include anticholinergics and metoclopramide. Evidence is limited on the safety or efficacy of the 5-HT3 inhibitors (e.g., ondansetron) for nausea and vomiting of pregnancy; however, because of their effectiveness in reducing chemotherapy-induced emesis, their use appears to be increasing

Safety[1-8, 15]
- **Akynzeo** (netupitant and palonosetron) has no FDA labeled contraindications
- **Anzemet** (dolasetron mesylate) is contraindicated in:
  - Patients known to have hypersensitivity to the drug
- **Emend** (aprepitant) is contraindicated in:
  - Known hypersensitivity to any component of this drug
  - Concurrent use with pimozide
- **Granisetron** is contraindicated in:
  - Patients with known hypersensitivity to the drug or any of its components
- **Sancuso** (granisetron) is contraindicated in:
  - Known hypersensitivity to granisetron or to any of the components of the transdermal system
- **Varubi** (rolapitant) is contraindicated in:
  - Use with CYP2D6 substrates with narrow therapeutic index (e.g., thioridazine and pimozide)
  - Pediatric patients less than 2 years of age because of irreversible impairment of sexual development and fertility in juvenile rats
- **Zuplenz/ondansetron** is contraindicated in:
  - Patients known to have hypersensitivity (e.g., anaphylaxis) to ondansetron or any components of the formulation
  - Concomitant use of apomorphine
  -

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8. Zuplenz prescribing information. Praelia Pharmaceuticals, Inc. August 2021.
9. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: ASCO Guideline Update. J Clin Oncol 2020 38:24/,2782-2797
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12. American College of Obstetrician and Gynecologists (ACOG). ACOG Practice Bulletin: Nausea and Vomiting of Pregnancy. *Obstet Gynecol. 2015;106(3):e12-e24*.
13. Apfel CC, Läärä E, Koivuranta M, Greim CA, Roewer N. A simplified risk score for predicting postoperative nausea and vomiting: conclusions from cross-validations between two centers. *Anesthesiology*. 1999;91:693–700.
14. Eberhart LH, Geldner G, Kranke P, et al. The development and validation of a risk score to predict the probability of postoperative vomiting in pediatric patients. *Anesth Analg*. 2004;99:1630–1637.
15. Ondansetron tablets/orally disintegrating tablets prescribing information. Glenmark Pharmaceuticals Inc, USA. November 2021.

Antiemetic Step Therapy with Quantity Limit

TARGET AGENT(S)
Sancuso® (granisetron)
Zuplenz® (ondansetron)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Target Agent(s) will be approved when ONE of the following is met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

    OR
2. The patient's medication history includes use of ONE generic oral 5HT-3 antiemetic agent (e.g., granisetron, ondansetron)
    OR
3. BOTH of the following:
    A. The prescriber has stated that the patient has tried at least ONE generic oral 5HT-3 antiemetic agent
    AND
    B. Generic oral 5HT-3 antiemetic agents were discontinued due to lack of effectiveness or an adverse event

    OR
4. The patient has an intolerance or hypersensitivity to ONE generic oral 5HT-3 antiemetic agent (e.g., granisetron, ondansetron)
    OR
5. The patient has an FDA labeled contraindication to ALL generic oral 5HT-3 antiemetic agents
    OR
6. The prescriber has provided documentation that ALL generic oral 5HT-3 antiemetic agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit section.

Antiemetic Agents Quantity Limit

TARGET AGENT(S)
Akynzeo® (netupitant/palonosetron)
Anzemet® (dolasetron)
Emend® (aprepitant)[c]
granisetron[b]
ondansetron ODT[b]
Sancuso® (granisetron)
Varubi® (rolapitant)
Zofran® (ondansetron)[a]
Zuplenz® (ondansetron)

a - generic available and included in quantity limit program
b - available as generic only
c - Emend 40 mg capsules are not included in this program due to use for postoperative nausea and vomiting only

QUANTITY LIMIT TARGET AGENT(S) - RECOMMENDED LIMITS (Limits allow for at least 7 days of cancer chemotherapy or radiotherapy)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Akynzeo (netupitant/palonosetron)			
300 mg / 0.5 mg capsule	50309902290120	M, N, O, or Y	2 capsules/30 days
Anzemet (dolasetron)			
50 mg tablet	50250025200320	M, N, O, or Y	7 tablets/30 days
100 mg tablet	50250025200330	M, N, O, or Y	7 tablets/30 days
Emend (aprepitant)[c]			
80 mg capsule[a]	50280020000120	M, N, O, or Y	4 capsules/30 days
125 mg capsule[a]	50280020000130	M, N, O, or Y	2 capsules/30 days
Emend Therapy Pack (1x125 mg capsule, 2x80 mg capsules)[a]	50280020006320	M, N, O, or Y	6 capsules (2 therapy packs)/30 days
125mg/5mL oral suspension	50280020001930	M, N, O, or Y	6 single-use kits/30 days
granisetron[b]			
1 mg tablet	50250035100310	M, N, O, or Y	14 tablets/30 days
ondansetron ODT[b]			
4 mg orally disintegrating tablet	50250065007220	M, N, O, or Y	21 tablets/30 days
8 mg orally disintegrating tablet	50250065007240	M, N, O, or Y	21 tablets/30 days
Sancuso (granisetron)			
3.1 mg/24 hours patch	50250035005920	M, N, O, or Y	2 patches/30 days
Varubi (rolapitant)			
90 mg tablet	5028005020B720	M, N, O, or Y	4 tablets/30 days
Zofran (ondansetron)[a]			
4 mg tablet	50250065050310	M, N, O, or Y	21 tablets/30 days
8 mg tablet	50250065050320	M, N, O, or Y	21 tablets/30 days
24 mg tablet[b]	50250065050340	M, N, O, or Y	1 tablet/30 days
4 mg/5 mL oral solution	50250065052070	M, N, O, or Y	
Zuplenz (ondansetron)			
4 mg oral soluble film	50250065008220	M, N, O, or Y	20 films (2 boxes of 10)/30 days
8 mg oral soluble film	50250065008240	M, N, O, or Y	20 films (2 boxes of 10)/30 days

a - generic available and included in quantity limit program
b - available as generic only
c - Emend 40 mg capsules are not included in this program due to use for postoperative nausea and vomiting only

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantity limit for **Anzemet, granisetron, Zofran/ondansetron/ondansetron ODT, or Zuplenz** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
2. The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month
   OR
3. The patient has delayed emesis in highly emetogenic chemotherapy
   OR
4. The patient has hyperemesis gravidarum
   OR
5. The patient has radiation therapy induced nausea and vomiting for radiation treatment that extends beyond 7 days per month
   OR
6. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity

Length of Approval: 12 months

Quantity limit for **Sancuso** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
2. The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 14 days per month
   OR
3. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity

Length of Approval: 12 months

Quantity limit for **Akynzeo**, **Emend/aprepitant, or Varubi** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
2. The patient has cancer chemotherapy related nausea and vomiting and the patient will be receiving chemotherapy more than 7 days per month
   OR
3. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity

Length of Approval: 12 months