

# Medical Policy

## Utilization Management and Clinical Medical Policy

<b>Policy Name:</b> Antiemetic - Parenteral Administration in Home Setting	<b>Policy Number:</b> MP-ME-FP-09-25	<b>Scope:</b> <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM MultiHealth	<b>Origination Date:</b> 08/22/2025 <b>Last Review Date:</b> 08/22/2025	<b>Frequently Revision:</b> Annual Page: 1 of 9
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### Service Category:

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|--|--|
| <input type="checkbox"/> Anesthesia                          | <input checked="" type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery                             | <input type="checkbox"/> Evaluation and Management Services          |
| <input type="checkbox"/> Radiology Procedures                | <input type="checkbox"/> DME/Prosthetics or Supplies                 |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input type="checkbox"/> Other: _____                                |

### Service Description:

This medical policy establishes clinical criteria for the administration of parenteral antiemetic medications at home, for the purpose of controlling moderate to severe nausea and vomiting in patients who cannot receive oral treatment. Home administration must be coordinated by a licensed clinical provider, as part of a prescribed, safe, evidence-based treatment plan.

This policy specifically includes **two classes** of antiemetic drugs:

#### A. Serotonin receptor antagonists (5HT3):

These drugs block 5HT3 receptors in the gastrointestinal tract and central nervous system, reducing nausea and vomiting induced by chemotherapy, radiation therapy, or surgery [1,11] Includes:

- Ondansetron (Zofran®)
- Granisetron (Kytril®, Sancuso®)
- Palonosetron (Aloxi®)

#### B. Dopaminergic antagonists (D2 receptors):

They work by blocking dopaminergic receptors in the central nervous system and are useful in the management of nausea from multiple causes, including gastroparesis, migraine, chronic diseases, and palliative care. Includes:

- Metoclopramide (Reglan®)
- Prochlorperazine (Compazine®)

#### General note:

Any use of the medicines listed in this policy that does not correspond to the expressly established indications must be evaluated in accordance with the Medical Policies in force and/or the pre-authorization criteria defined by the Pharmacy Department.

### Background Information:

Nausea and vomiting can represent debilitating complications in oncological, palliative and chronic patients. In some cases, oral antiemetics are ineffective or inappropriate, and intravenous use in an out-of-hospital setting is required to maintain treatment adherence and quality of life. Home administration of antiemetics should be safe, effective, and clinically justified.

The main pharmacological groups used in this context include [2,11]:

#### 5HT3 serotonin receptor antagonists:

5-HT3 receptor antagonists, informally known as "setrons," are a class of drugs that act as antagonists of 5-HT3 receptors, a subtype of serotonin receptor found in the terminals of the vagus nerve and in certain areas of the brain. With the notable exceptions of alosetron and cilansetron, which are used in the treatment of irritable bowel syndrome, all 5-HT3 receptor antagonists are antiemetics, which are used in the prevention and treatment of nausea and vomiting. They are particularly effective in controlling nausea and vomiting produced by cancer chemotherapy and are considered the gold standard for this purpose [2].

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5-HT3 antagonists are also indicated in the prevention and treatment of radiation-induced nausea and vomiting (LVN), when necessary, and postoperative nausea and vomiting (PONV). Although they are more effective at controlling CINV (in which they stop symptoms completely in up to 70% of people and reduce them in the remaining 30%), they are just as effective as other agents for CINV. Current evidence suggests that 5-HT3 antagonists are ineffective in controlling motion sickness. A randomized, placebo-controlled trial of ondansetron to treat motion sickness in air ambulance personnel showed subjective improvement, but it was not statistically significant [2].

Existen pocos efectos secundarios relacionados con el uso de antagonistas 5-HT3; los más comunes son estreñimiento o diarrea, dolor de cabeza y mareos. A diferencia de los antihistamínicos con propiedades antieméticas como la ciclizina, los antagonistas 5-HT3 no producen sedación, ni causan efectos extrapiramidales, como a veces lo hacen las fenotiazinas (como la proclorperazina).

### Dopaminergic antagonists D2 [3]:

A dopamine antagonist, also known as an antidopaminergic and dopamine receptor antagonist (DRA), is a type of drug that blocks dopamine receptors by antagonizing the receptor. Most antipsychotics are dopamine antagonists and, as such, have found utility in the treatment of schizophrenia, bipolar disorder, and stimulant psychosis. Several other dopamine antagonists are antiemetics that are used in the treatment of nausea and vomiting. Dopamine Antagonists Used to Treat Nausea and Vomiting

- Domperidone is a peripherally selective dopamine D2 receptor antagonist used as an antiemetic, gastroprokinetic, and galactagogue agent.
- Bromopride binds to enteric D2 receptors and treats gastroparesis.
- Metoclopramide also treats gastroparesis

Intravenous administration provides the most rapid onset of action, particularly for severe or acute emesis, because the bioavailability of the drug is directly related to the circulatory system and is rapidly delivered to the site of action. Ondansetron and metoclopramide are frequently given in this manner in clinical settings. IM injections offer an alternative for patients who cannot tolerate oral medications and where intravenous access is not readily available. IM administration can be painful, can result in unpredictable absorption of the drug, and carries the risk of sterile abscess formation or tissue fibrosis [1].

The American Society of Clinical Oncology (ASCO) guidelines suggest administering granisetron extended-release subcutaneous injection or granisetron transdermal patch to patients undergoing a multiday chemotherapy cycle instead of administering a 5-HT3 receptor antagonist each day of the multiday cycle [11].

### Improve health care team outcomes:

Nausea and vomiting can negatively affect a patient's health and quality of life, especially when induced by cancer treatment. CINV is associated with increased health care costs. An interdisciplinary team can ensure that antiemetic guidelines are properly followed. Doctors, physician assistants, and nurse practitioners can identify patient-specific factors that increase the risk of CINV, such as female gender, age younger than 50, and anxiety. Nurses may evaluate the patient's history to anticipate nausea and vomiting and advocate for premedicating patients. Pharmacists can identify the emetogenic risk of cancer drugs, identify drug interactions and adverse effects, and recommend appropriate monitoring parameters [11].

### Most Common Adverse Reactions [11]:

- Headache (9% to 27%)
- Fatigue (9% to 13%)
- Malaise (9% to 13%)
- Constipation (6% to 11%)

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### Medical Necessity Guidelines:

The indication for parenteral antiemetic short term should be supported by documented medical necessity, and its administration should be carried out according to standardized protocols for preparation, surveillance, and transition to oral therapy [4-8]. It is considered medically necessary when it meets the following:

A. Conditions Patient Must Meet to Qualify for Coverage of Home Health Services [9]:

- Being homebound **and**;
- Under the care of a physician or licensed professional **and**;
- Receive services under an established plan of care and periodically reviewed by a physician or licensed professional **and**;
- Needing skilled nursing care on an intermittent basis **and**;

B. Documented diagnosis of an indicated condition requiring a parenteral antiemetic [9] **and**;

C. Medical reason that prevents the drug from being taken orally [9] **and**;

D. Presentation of the Medication as directed and recommended by the National Home Infusion Association (NHIA,2025):

#### Serotonin receptor antagonists (5HT3) approved:

Medication (generic – brand)	Indication and usage	Dosage and Administration (IV or IM)	Source
<b>Ondansetron - Zofran®</b>	<ul style="list-style-type: none"> <li>• Prevention of nausea and vomiting associated with initial or repeated cycles of highly emetogenic chemotherapy, such as high-dose cisplatin. The efficacy of a single dose of 32 mg after 24 h has not been demonstrated.</li> <li>• Prevention of postoperative nausea and/or vomiting. Routine prophylaxis is not recommended in patients with a low probability of presenting these symptoms. However, when it is critical to avoid these complications, Zofran Injection is recommended even if the risk is low.</li> <li>• In patients who did not receive prior prophylaxis and develop nausea and/or vomiting after surgery, Zofran Injection may be given to prevent further episodes</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Adults:</b> single dose of 32 mg IV infused over 15 min, started 30 min before emetogenic treatment.</li> <li>• Alternatively: three doses of 0.15 mg/kg IV, each administered as a 15-min infusion, starting 30 min before, and repeated at 4 and 8 h after the first dose.</li> <li>• <b>Product Compatibility:</b> It should not be mixed with solutions whose physical or chemical compatibility is not established, especially alkaline solutions, as precipitates may form.</li> </ul>	FDA Label [4]
<b>Granisetron - Kytril®, Sancuso®</b>	- Prevention of nausea and/or vomiting during initial or repeated cycles of	• <b>Adults:</b> 10 mcg/kg IV, within 30 min prior to initiation of chemotherapy; administer only on the day chemotherapy is applied.	FDA Label [5]

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	<p>highly emetogenic chemotherapy, including high-dose cisplatin.</p> <ul style="list-style-type: none"> <li>Prevention and treatment of postoperative nausea and vomiting in adults:</li> <li>Routine prophylaxis is not recommended in patients with a low probability of presenting these symptoms.</li> <li>If it is critical to avoid nausea or vomiting after surgery, KYTRIL® Injection is recommended even at low risk, and can be used for both prevention and treatment.</li> </ul>	<ul style="list-style-type: none"> <li>Infusion preparation: Administer undiluted within 30 s, or diluted in 0.9% NaCl or 5% dextrose and infuse within 5 min.</li> <li>Prepare immediately. Stable up to 24 hrs if diluted and stored at room temperature with normal lighting.</li> <li>Do not mix with other drugs whose compatibility is not established.</li> <li>Visually inspect before administration for possible presence of particles or discoloration.</li> <li><b>Pediatric patients (2–16 years):</b> recommended dose of 10 mcg/kg.</li> <li><b>Geriatric patients</b> or patients with renal or hepatic impairment: no dose adjustment is required.</li> </ul> <p><b>Prevention and treatment of postoperative nausea:</b></p> <ul style="list-style-type: none"> <li><b>Adults:</b> 1 mg IV undiluted in 30 s, before induction or reversal of anesthetic.</li> <li>For treatment of vomiting or nausea after surgery: 1 mg IV undiluted in 30 s.</li> <li><b>Pediatric patients &lt; 2 years:</b> no safety or efficacy has been established.</li> </ul>	
<b>Palonosetron</b> <b>Aloxi®</b>	<ul style="list-style-type: none"> <li><b>In adults:</b> Prevention of acute and delayed nausea and vomiting in moderate or highly emetogenic chemotherapy, including initial and repeated cycles.</li> <li>Prevention of postoperative nausea and vomiting (PONV) for up to 24 h after surgery; efficacy beyond that period has not been demonstrated.</li> <li>Routine prophylaxis is not recommended in low-risk patients; but it should be considered when symptoms should be avoided even with</li> </ul>	<p><b>Chemotherapy (CINV):</b></p> <ul style="list-style-type: none"> <li><b>Adults:</b> 0.25 mg IV as a single dose, infused in 30 seconds, approximately 30 minutes prior to the start of chemotherapy.</li> <li><b>Pediatric (1 month to &lt;17 years):</b> 20 µg/kg IV, maximum 1.5 mg, infused in 15 minutes, approximately 30 minutes prior to initiation of chemotherapy.</li> </ul> <p><b>Postoperative nausea and vomiting (PONV):</b></p> <ul style="list-style-type: none"> <li><b>Adults:</b> 0.075 mg IV as a single dose,</li> </ul>	FDA Label [6]

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	<p>low incidence.</p> <ul style="list-style-type: none"> <li>• <b>In pediatric patients (1 month to &lt;17 years):</b></li> <li>• Prevention of acute nausea and vomiting associated with initial or repeated cycles of highly emetogenic chemotherapy.</li> </ul>	<p>administered over 10 seconds immediately prior to anesthetic induction; efficacy only up to 24 h.</p>	
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### Antiemetics Dopaminergic antagonists (D2 receptors):

Medication (generic-brand)	Indication and usage	Dosage and administration (IV or IM)	Source
<b>Metoclopramide (Reglan®)</b>	<ul style="list-style-type: none"> <li>• Diabetic gastroparesis – relief of symptoms associated with acute or recurrent gastric stasis.</li> <li>• Prophylaxis of vomiting by emetogenic chemotherapy.</li> <li>• Prevention of postoperative nausea and vomiting where nasogastric suction is not desirable.</li> <li>• It facilitates the intubation of the small intestine in patients (adult or pediatric) if the tube does not pass the pylorus with conventional maneuvers.</li> <li>• It stimulates gastric emptying and intestinal barium transit in radiological studies where delayed emptying makes visualization difficult.</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Diabetic gastroparesis (severe symptoms):</b> dose of 10 mg IV slowly over 1–2 min; It can be given for up to 10 days before transitioning to oral.</li> <li>• Prevention of vomiting by emetogenic chemotherapy:</li> <li>• Slow IV infusion <math>\geq</math> 15 min, starting 30 min before treatment.</li> <li>• Repeat: two doses every 2 h, then three doses every 3 h.</li> <li>• Initial Dosing: <ul style="list-style-type: none"> <li>• 2 mg/kg if highly emetogenic drugs (such as cisplatin) are used.</li> <li>• 1 mg/kg for less emetogenic regimens.</li> </ul> </li> <li>• If the dose is <math>&gt;</math>10 mg, dilute in 50 mL of parenteral solution.</li> <li>• Diluted preparations (saline, Ringer, etc.) can be stored for up to 48 hours protected from light, or frozen for up to 4 weeks (saline).</li> <li>• <b>Prevention of postoperative nausea and vomiting (PONV):</b> <ul style="list-style-type: none"> <li>• Administer 10 mg IM near the end of surgery; Up to 20 mg can be used if needed.</li> </ul> </li> <li>• Facilitation of small bowel intubation: <ul style="list-style-type: none"> <li>• If the tube does not pass the pylorus after 10 min, administer a single IV dose in 1–2 min: <ul style="list-style-type: none"> <li>• Adults and pediatrics <math>\geq</math>14 years: 10 mg.</li> <li>• Pediatric 6–14 years: 2.5–5 mg.</li> <li>• Pediatric <math>&lt;</math>6 years: 0.1 mg/kg base.</li> </ul> </li> </ul> </li> </ul>	FDA Label <a href="#">[7]</a>

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		<ul style="list-style-type: none"> <li>• <b>Radiological examinations (barium transit):</b></li> <li>• Use the same dosage as bowel intubation when delayed emptying interferes with the study.</li> <li>• <b>Renal or hepatic impairment:</b> In patients with CrCl &lt; 40 mL/min, start with approximately half the usual dose, and adjust for clinical response.</li> </ul>	
<b>Prochlorperazine (Compazine®)</b>	• Control severe nausea and vomiting.	<b>To control severe nausea and vomiting</b> <ul style="list-style-type: none"> <li>• IM: 5–10 mg (1–2 mL), repeat every 3–4 hours as needed. Maximum daily dose: 40 mg.</li> <li>• Slow IV: 2.5–10 mg (0.5–2 mL), velocity ≤ 5 mg/minute; do not use fast bolus. Single dose ≤ 10 mg; Maximum daily total: 40 mg.</li> <li>• Hypotension possible if administered by IV.</li> </ul>	FDA Label [8]

**Not Medical Necessity:**

Home administration of Antiemetic Parenteral **will not be considered medically necessary** in the following circumstances:

1. Availability of functional oral route: When the patient can tolerate and absorb medications orally safely and effectively.
3. Conditions not related to gastric hypersecretion or without a validated diagnosis.
4. Request based solely on patient preference or logistical convenience, with no clinical judgment justifying home IV administration.

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### Limits or Restrictions:

- This request requires going through the evaluation and determination process.
1. Prochlorperazine: Subcutaneous administration is not advisable because of local irritation
2. Table of contraindications warnings and precautions:

#### Serotonin receptor antagonists (5HT3):

Medication (generic – brand)	Contraindication	Warnings and precautions	Source
<b>Ondansetron - Zofran®</b>	The concomitant use of apomorphine with ondansetron is contraindicated based on reports of profound hypotension and loss of consciousness when apomorphine was administered with ondansetron. ZOFRAN® Injection is contraindicated for patients known to have hypersensitivity to the drug.	•Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonists.	FDA Label [4]
<b>Granisetron - Kytril®, Sancuso®</b>	Contraindicated in patients with known hypersensitivity to the drug or to any of its components.	•Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonists.	FDA Label [5]
<b>Palonosetron- Aloxi®</b>	Hypersensitivity to the drug or any of its components.	<ul style="list-style-type: none"> <li>• Hypersensitivity reactions, including anaphylaxis, have been reported with or without known hypersensitivity to other selective 5-HT3 receptor antagonists.</li> <li>• Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs.</li> </ul>	FDA Label [6]

#### Antiemetics Dopaminergic antagonists (D2):

Medication (generic – brand)	Indication and usage	Dosage and Administration	Source
<b>Metoclopramide -Reglan®</b>	<ul style="list-style-type: none"> <li>• Gastrointestinal bleeding, obstruction, or perforation</li> <li>• Pheochromocytoma (risk of hypertensive crisis)</li> <li>• Hypersensitivity to medication</li> <li>• Epilepsy or use of drugs that cause extrapyramidal reactions</li> </ul>	Tardive Dyskinesia (severe and irreversible movement disorder) Avoid use >12 weeks unless clinically justified	FDA Label [7]
<b>Prochlorperazine - Compazine®</b>	<ul style="list-style-type: none"> <li>• Hypersensitivity to phenothiazines</li> <li>• Comatose state</li> <li>• Use with CNS depressants (alcohol, barbiturates, narcotics)</li> <li>• Pediatric surgery</li> <li>• Children &lt;2 yrs or &lt;20 lbs</li> <li>• Pediatric use with no set dosage</li> </ul>	Higher mortality in elderly people with dementia-related psychosis	FDA Label [8]

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### Codes Information:

#### ICD-10 Diagnostic Codes:

Codes	Description
R11.2	Nausea with vomiting
R11.0	Nausea
R11.10	Vomiting without nausea
K31.84	Gastroparesis

#### HCPCS Codes:

Codes	Description
J8655	Granisetron Injection, 0.1 mg
J2469	Ondansetron Injection 1 mg

#### CPT Codes:

Codes	Description
96365	Administration of medication by intravenous infusion, initial, up to 1 hour, substance or drug (except chemotherapy or biological agents)
96366	Under Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration).
96367	Under Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration).
96368	Concurrent infusion (for multiple substances)
96374	Therapeutic, prophylactic or diagnostic injection; IV push, single or initial substance/drug
96375	Under Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration).

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.



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- ondansetron hydrochloride. Fda.gov. [cited 2025 Jul 23]. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/020007s040,020403s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020007s040,020403s018lbl.pdf)
- Hydrochloride G. KYTRIL (granisetron hydrochloride) Injection is an antiemetic and antiemetic agent. Chemically it is endo-N-(9-methyl-9-azabicyclo [3.3.1] non-3-yl)-1-methyl-1H-indazole-3-carboxamide hydrochloride with a molecular weight of 348.9 (312.4 free base). Its empirical formula is C18H24NO•HCl, while its chemical structure is: [Internet]. Fda.gov. [cited 2025 Jul 23]. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020239s021,020305s014,021238s007lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020239s021,020305s014,021238s007lbl.pdf).
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- Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Pub. 100-02, Chapter 7 – Home Health Services; section 30 Conditions Patient Must Meet to Qualify for Coverage of Home Health Services (Rev. 10438, Issued 11-06-20; Effective 03-01-20; Implementation 01-11-21). Baltimore: CMS.
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### Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
<b>Superseded</b>	This policy supersedes two previous policy (MP-ME-FP-04-24 // MP-ME-FP-05-24). The new version organizes antiemetic drugs by pharmacological class and aligns them with NHIA recommendations. All sections of the policy were standardized and aligned, including clinical criteria, indications, limitations, coding and references. This version is fully compliant with FDA-approved labeling for intravenous medications and current NHIA standards for home infusion therapy.	Not Required	08/22/2025