

Medical Necessity Guidelines

For 5-HT3 receptor antagonist IV administration to be considered medically necessary in a home setting, the following criteria generally must be met:

- **Patient Eligibility:**
 - The patient has been diagnosed with a condition that leads to severe, intractable nausea and vomiting, such as chemotherapy-induced nausea and vomiting (CINV), radiation-induced nausea and vomiting (RINV), or post-operative nausea and vomiting (PONV).
 - The patient has a history of inadequate response to oral or alternative antiemetic therapies.
 - The patient's condition is stable and appropriate for home care as determined by a healthcare provider.
 - The patient or caregiver can manage home IV administration, or there is access to home health services.

- **Clinical Justification:**
 - The patient's need for frequent or ongoing IV antiemetic therapy has been documented.
 - The patient's nausea and vomiting are of a severity that interferes with oral intake or the use of oral medications.
 - Continued IV administration is anticipated to improve the patient's quality of life, reduce hospital visits, or manage symptoms more effectively.

- **Prescriber Orders:**
 - The IV medication is prescribed by a licensed healthcare provider who has determined that home administration is necessary and appropriate for the patient.
 - There is a clear treatment plan in place, including frequency and dosage, and access to a trained home healthcare provider, if needed.

- **Common 5-HT3 Receptor Antagonists Used for IV Administration at home:**
 - Ondansetron (Zofran)
 - Granisetron (Kytril)
 - Palonosetron (Aloxi) (for ER and hospital-based only)
 - Dolasetron (Anzemet) (for ER and hospital-based only)

- **Indications for Use:**
 - Prevention and treatment of chemotherapy-induced nausea and vomiting (CINV)
 - Prevention of radiation-induced nausea and vomiting (RINV)
 - Management of post-operative nausea and vomiting (PONV)

• Clinical Guidelines:

- National Comprehensive Cancer Network (NCCN) guidelines provide recommendations on the use of antiemetics, including 5-HT3 receptor antagonists, for patients undergoing cancer treatment.
- The American Society of Clinical Oncology (ASCO) also offers guidance on the appropriate use of antiemetic medications.
- FDA approve dose for administration IV at home service.
 - i. The FDA does not explicitly approve specific doses for home administration of drugs but approves medications and their general use (e.g., formulations, dosing, and administration routes). However, FDA-approved doses for IV administration of 5-HT3 receptor antagonists are determined by clinical guidelines, and physicians can prescribe these medications for home use based on individual patient needs. Below are common FDA-approved IV doses of 5-HT3 receptor antagonists, which can be administered in a home setting when medically necessary.
 1. Ondansetron (Zofran)
 - a. FDA-Approved IV Dose for Chemotherapy-Induced Nausea and Vomiting (CINV):
 - i. For highly emetogenic chemotherapy: 0.15 mg/kg administered every 4 hours, starting 30 minutes before chemotherapy.
 - b. For moderately emetogenic chemotherapy:
 - i. 8 mg as a single IV dose over 15 minutes, starting 30 minutes before chemotherapy.
 - c. Postoperative Nausea and Vomiting (PONV):
 - i. 4 mg IV as a single dose administered over 2 to 5 minutes, either at the end of surgery or prior to anesthesia induction.
 2. Granisetron (Kytril)
 - a. FDA-Approved IV Dose for Chemotherapy-Induced Nausea and Vomiting (CINV):
 - i. 10 mcg/kg, administered within 30 minutes before chemotherapy. Alternatively, a single dose of 1 mg may be given IV over 5 minutes before chemotherapy.
 3. Palonosetron (Aloxi) (ER and hospital-based only)
 - a. FDA-Approved IV Dose for Chemotherapy-Induced Nausea and Vomiting (CINV):
 - i. 0.25 mg IV administered as a single dose over 30 seconds, 30 minutes before chemotherapy.
 - b. Postoperative Nausea and Vomiting (PONV):
 - i. 0.075 mg IV as a single dose over 10 seconds, administered immediately before the induction of anesthesia.
 4. Dolasetron (Anzemet) (ER and hospital-based only)
 - a. FDA-Approved IV Dose for Chemotherapy-Induced Nausea and Vomiting (CINV):
 - i. 1.8 mg/kg or 100 mg as a single dose, administered 30 minutes before chemotherapy.

- Important considerations for Home Administration:
 - i. Dosage Adjustments: While these are standard FDA-approved doses for IV use, home administration must be tailored based on patient-specific factors such as response to treatment, side effects, and clinical condition. A healthcare provider must assess the patient's eligibility for home administration.
 - ii. Safety: The home setting should have proper oversight, and the patient or caregiver must be trained in IV drug administration or have access to home healthcare professionals.
 - iii. Home Care Provider: Administration of IV medication at home generally requires collaboration with a home health agency to ensure sterile technique, correct dosing, and patient monitoring.
- The use of these medications at home for IV administration should be prescribed within the scope of FDA guidance, with the healthcare provider ensuring appropriate dosing, safety protocols, and follow-up care.

Limits or Restrictions

- Frequency of Administration:
 - i. Administration frequency is typically limited to what is necessary to control symptoms as per the prescribing physician's orders. Long-term or indefinite use may require ongoing reassessment of the patient's condition and therapy necessity.
- Duration of Therapy:
 - i. Home administration is often limited to the period of active treatment, such as during chemotherapy cycles. Prolonged use outside the prescribed period requires review for continued medical necessity.
- Supervision Requirements:
 - i. In some cases, home administration may require oversight by a home health nurse, particularly for the initial administration or if the patient/caregiver is inexperienced with IV therapy.
 - ii. Regular follow-ups or reassessment by the prescribing provider may be required to ensure therapy effectiveness and safety.
- Drug-Specific Restrictions:
 - i. Not all 5-HT3 receptor antagonists may be appropriate for home use, and administration might be limited to certain drugs in this class (e.g., ondansetron, granisetron) depending on the patient's medical condition.
- In summary:
 - i. 5-HT3 receptor antagonist IV administration at home is typically reserved for patients with severe nausea and vomiting that cannot be managed by other means. It requires careful assessment to ensure the appropriateness and safety of the therapy, with limits based on clinical need and oversight.

Reference Information

The dosing and administration guidelines provided above for 5-HT3 receptor antagonists are based on FDA labeling information and widely recognized clinical guidelines. Here are the references for the information:

- Ondansetron (Zofran):
 - Source: FDA Drug Label for Ondansetron (Zofran), available through the [FDA's Drugs@FDA database](#)
 - Clinical Guidelines: **National Comprehensive Cancer Network (NCCN) Antiemesis Guidelines.**
- Granisetron (Kytril):
 - Source: FDA Drug Label for Granisetron (Kytril), available through the [FDA's Drugs@FDA database](#)
- Palonosetron (Aloxi) (ER and hospital-based only)
 - Source: FDA Drug Label for Palonosetron (Aloxi), available through the [FDA's Drugs@FDA database](#)
 - Additional Clinical Recommendations: **American Society of Clinical Oncology (ASCO) Antiemetic Guidelines.**
- Dolasetron (Anzemet): (ER and hospital-based only)
 - Source: FDA Drug Label for Dolasetron (Anzemet), available through the [FDA's Drugs@FDA database](#)
- Clinical Guidelines Supporting Use:
 - **National Comprehensive Cancer Network (NCCN):** Antiemesis Guidelines provide evidence-based recommendations for the prevention and treatment of nausea and vomiting associated with cancer treatments. [NCCN.org](#)
 - **American Society of Clinical Oncology (ASCO):** Guidelines for the use of antiemetic agents, including 5-HT3 receptor antagonists, in clinical practice
 - **American Society of Clinical Oncology (ASCO):** ASCO Antiemetic Guidelines Update 2020.
- **Supportive Oncology by M. Markman and L. C. Payne, 2015, Chapter :** "Management of Chemotherapy-Induced Nausea and Vomiting, pages(75-100): Relevant to guidelines for 5-HT3 receptor antagonists

Policy History

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Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
INTERNAL POLICY	5-HT3 receptor antagonists are a class of medications primarily used to prevent and treat nausea and vomiting, especially in patients undergoing chemotherapy, radiation therapy, or surgery		12/20/2024