

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Antiemetic 5-HT3, NK1 and Other Select Agents, Non-Injectable PDL Edit
<b>First Implementation Date:</b>	October 6, 2004
<b>Proposed Date:</b>	December 17, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** The 5HT3 receptor antagonists are indicated for the prevention and treatment of nausea and vomiting associated with chemotherapy and radiotherapy. Diclegis® (doxylamine/pyridoxine) is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Metoclopramide is indicated for diabetic gastroparesis and gastroesophageal reflux, as well as off-label use for treating nausea and vomiting associated with chemotherapy and radiation. Neurokinin-1 (NK1) receptor antagonists have indications that include prevention and treatment of nausea and vomiting associated with chemotherapy and radiotherapy and post-operative nausea and vomiting. The management of chemotherapy-induced nausea and vomiting is a critical aspect of treating cancer patients. The advent of agents within this therapeutic class was a significant breakthrough for the practice of oncology. However, because of the increased cost of these products, it is essential that therapy is appropriately monitored, and prudently utilized for the appropriate patient population.

Total program savings for the PDL classes will be regularly reviewed.

<b>Program-Specific information:</b>	<b>Preferred Agents</b>	<b>Non-Preferred Agents</b>
	<ul style="list-style-type: none"> <li>• Aprepitant</li> <li>• Metoclopramide Soln/Tabs</li> <li>• Ondansetron ODT/Soln/Tabs</li> </ul>	<ul style="list-style-type: none"> <li>• Akynzeo® Caps</li> <li>• Anzemet®</li> <li>• Bonjesta®</li> <li>• Diclegis®</li> <li>• Doxylamine/Pyridoxine</li> <li>• Emend® Caps/Pwd Packet</li> <li>• Granisetron Tabs</li> <li>• Metoclopramide ODT</li> <li>• Reglan®</li> <li>• Sancuso®</li> <li>• Varubi® Tabs</li> <li>• Zofran® ODT/Soln/Tabs</li> <li>• Zuplenz®</li> </ul>

- Type of Criteria:**     Increased risk of ADE                       Preferred Drug List  
 Appropriate Indications                       Clinical Edit
- Data Sources:**         Only Administrative Databases                       Databases + Prescriber-Supplied

### Setting & Population

- Drug class for review: Antiemetic 5-HT3, NK1 and Other Select Agents, Non-Injectable
- Age range: All appropriate MO HealthNet participants

### Approval Criteria

- For aprepitant: maximum quantity of 3 doses per chemotherapy course **OR**
- Failure to achieve desired therapeutic outcomes with a trial on 1 or more preferred agents:
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Diclegis and Bonjesta: adequate therapeutic trial of doxylamine (trial defined as 60/90 days)
- For Zuplenz: Clinical Consultant Review required for medical necessity of therapy

### Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Dosing Limitations
ANZEMET 100 MG	DOLASETRON	1 tablet per day
ANZEMET 50 MG	DOLASETRON	1 tablet per day
GRANISETRON 1 MG	GRANISETRON	2 tablets per day
ZOFRAN 24 MG	ONDANSETRON	1 tablet per day
ZUPLENZ 4 MG	ONDANSETRON	3 films per day
ZUPLENZ 8 MG	ONDANSETRON	3 films per day

### Required Documentation

- Laboratory Results:                          Progress Notes:
- MedWatch Form:                              Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Drug Effectiveness Review Project – Drug Class Review on Antiemetics - Newer. Center for Evidence-Based Policy, Oregon Health & Science University; January 2009; Expanded Scan August 2018.
2. Evidence-Based Medicine and Fiscal Analysis: "Antiemetic Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2020.
3. Evidence-Based Medicine Analysis: "Antiemetics - 5-HT3, THC Derivatives, NK1 & Other Agents", UMKC-DIC; September 2020.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
5. USPDI, Micromedex; 2020.
6. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.