



SmartPA Criteria Proposal

Drug/Drug Class:	Antiemetic 5-HT3, NK1 and Other Select Agents PDL Edit
First Implementation Date:	October 6, 2004
Revised Date:	April 2, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" 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. 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 right patient population. 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, as above, because of the increased cost of these products, it is essential that therapy is appropriately monitored, and prudently utilized for the right patient population.

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

Program-Specific information:

Preferred Agents	Non-Preferred Agents
<ul style="list-style-type: none">• Aprepitant Caps• Metoclopramide Soln/Tabs• Ondansetron• Palonosetron Vial	<ul style="list-style-type: none">• Akynzeo®• Aloxi®• Anzemet®• Bonjesta®• Cinvanti®• Diclegis®• Doxylamine/Pyridoxine• Emend®• Fosaprepitant Vial• Granisetron• Metoclopramide ODT• Palonosetron Syringe• Reglan®• Sancuso®• Sustol®• Varubi®• Zofran®• Zuplenz®

Type of Criteria:

- Increased risk of ADE
- Appropriate Indications

- Preferred Drug List
- Clinical Edit

Data Sources:

- Only Administrative Databases

- Databases + Prescriber-Supplied

Setting & Population

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

Approval Criteria

- 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
- For Diclegis and Bonjesta:
 - Above criteria AND
 - Adequate therapeutic trial of doxylamine (trial defined as 60/90 days)
- For Aprepitant:
 - Maximum quantity of 3 doses per chemotherapy course
- For Zuplenz: Clinical Consultant Review required for medical necessity of therapy

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Lack of adequate trial on required preferred agents
- Claim exceeds dosing limitations:

Drug Description	Generic Equivalent	Max Units Per Day
Aloxi 0.25 mg/5 ml	Palonosetron	5 ml
Anzemet 100 mg	Dolasetron	1 tablet
Anzemet 50 mg	Dolasetron	1 tablet
Kytril 1 mg	Granisetron	2 tablets
Zofran 24 mg	Ondansetron	1 tablet
Zofran 4 mg	Ondansetron	3 tablets
Zofran 4 mg/5 ml	Ondansetron	30 ml
Zofran 8 mg	Ondansetron	3 tablets
Zofran ODT 4 mg	Ondansetron	3 tablets
Zofran ODT 8 mg	Ondansetron	3 tablets

Required Documentation

Laboratory Results:
 MedWatch Form:

Progress Notes:
 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 2019.
3. Evidence-Based Medicine Analysis: "Antiemetics - 5-HT3, THC Derivatives, NK1 & Other Agents", UMKC-DIC; September 2019.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2019.
5. USPDI, Micromedex; 2019.
6. Drug Facts and Comparisons On-line; 2019.