SmartPA Criteria Proposal

Drug/Drug Class:	Antiemetics, 5-HT3, NK1 and Other Select Non-Injectables PDL Edit
First Implementation Date:	October 6, 2004
Proposed Date:	December 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

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

Why Issue Selected: The 5-HT3 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.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Aprepitant Caps • Metoclopramide Soln/Tabs • Ondansetron ODT/Soln/Tabs	• Akynzeo® Caps • Anzemet® • Bonjesta® • Diclegis® • Doxylamine/Pyridoxine • Emend® Caps/Pwd Packet • Gimoti® • Granisetron Tabs • Metoclopramide ODT • Reglan® • Sancuso® • Zofran® Tabs

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: Antiemetics, 5-HT3, NK1 and Other Select Non-Injectables
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For aprepitant capsules: 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:	**X**
MedWatch Form:		Other:	

Disposition of Edit

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

Default Approval Period

6 months

References

- Evidence-Based Medicine and Fiscal Analysis: “Antiemetic Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.

- Evidence-Based Medicine Analysis: “Antiemetics - 5-HT3, THC Derivatives, NK1 & Other Agents”, UMKC-DIC; September 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.