POLICY NUMBER UM ONC_1035	**SUBJECT** 5HT$_3$ receptor antagonists (Zofran, Kytril, Anzemet, Aloxi, Akynzeo, Sancuso, Sustol)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 01/12/11, 02/27/12, 07/11/12, 06/01/13, 07/10/13, 07/24/14, 11/12/14, 12/17/15, 04/08/16, 05/24/16, 08/24/16, 05/10/17, 05/07/18, 07/10/19, 12/11/19, 03/11/20, 07/08/20	**APPROVAL DATE** July 8, 2020	**EFFECTIVE DATE** July 31, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 01/12/11, 02/27/12, 07/11/12, 06/01/13, 07/10/13, 07/24/14, 11/12/14, 12/17/15, 04/08/16, 05/24/16, 08/24/16, 05/10/17, 05/07/18, 07/10/19, 12/11/19, 03/11/20, 07/08/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for 5HT3 receptor antagonists (Zofran, Kytril, Anzemet, Aloxi, Akynzeo, Sancuso, Sustol) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. Antiemesis

a. Zofran (ondansetron) OR Kytril (granisetron), is being used in any of the following clinical situations:

i. Before highly emetogenic (> 90% frequency of emesis) chemotherapy

ii. Before moderate emetic risk chemotherapy (30-90% frequency in emesis)

iii. Before low or minimal emetic risk chemotherapy (< 30% frequency in emesis)

iv. Before radiation to the upper abdomen or total body irradiation

v. Treatment for nausea/vomiting induced by chemotherapy, immunotherapy, oral oncolytic therapy, targeted therapy, and radiation.

b. Aloxi (palonosetron) is being used in any of the following situations:

i. Before moderately/highly emetogenic chemotherapy (emetogenicity of agent/regimen is based on the antiemetic practice guideline from NCCN) **OR**

ii. Before low or minimal emetic risk chemotherapy in members who failed or are intolerant to or have a contraindication to Zofran (ondansetron) or Kytril (granisetron).

c. Akynzeo (netupitant-palonosetron) is being used before moderate/highly emetic risk chemotherapy.

d. Sancuso (granisetron PATCH) is being used before moderate/highly emetogenic risk chemotherapy.

e. Sustol (granisetron extended release) is being used as **ONE** of the following:

i. Before or after highly emetogenic chemotherapy, for example cisplatin or anthracycline and cyclophosphamide combination chemotherapy regimens **OR**

ii. Before moderate/highly emetic risk chemotherapy in members who have failed or are intolerant to any 5HT3+ agent PLUS (fosaprepitant or aprepitant) combination.

III. EXCLUSION CRITERIA

1. Sustol is being used without failure, intolerance, or contraindications to any 5HT3 + Emend (fosaprepitant/aprepitant) combination.
2. Aloxi and Akynzeo are being used for prevention of radiation induced nausea and vomiting.
3. Dose exceeds the maximum single dose limits for IV Zofran 16 mg, Oral Zofran 24 mg, Kytril 1 mg IV/PO, Kytril 34.3 mg patch, Anzemet 100 mg, Aloxi 0.25 mg IV, Aloxi 0.5 mg PO, Akynzeo 300 mg/0.5 mg, and Sustol 10 mg.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Zofran prescribing information. GlaxoSmithKline Research. Triangle Park, NC. 2018.
2. Kytril prescribing information. Roche Laboratories Inc. 340 Kingsland Street Nutley, New Jersey. 2019.
3. Aloxi prescribing information. Eisai Inc. Woodcliff Lake, NJ. 2018.
4. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminister, NJ. 2019.
5. Sustol prescribing information. Heron Therapeutics. Redwood City, CA. 2017.

6. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ 2018.
7. Clinical Pharmacology Elsevier Gold Standard. 2020.
8. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
9. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.
10. FDA drug safety communication: abnormal heart rhythms associated with use of anzemet (dolasetron mesylate). http://www.fda.gov/Drugs/DrugSafety/ucm237081.htm Accessed December 20, 2010.
11. Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. Journal of Clinical Oncology 2017 35:28, 3240-3261.