

# Drug Policy:

## 5HT<sub>3</sub> Receptor Antagonists

<b>POLICY NUMBER</b> UM ONC_1035	<b>SUBJECT</b> 5HT <sub>3</sub> receptor antagonists (Zofran, Granisetron, Anzemet, Aloxi, Akynzeo, Sancuso, Sustol)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 3</b>
<b>DATES COMMITTEE REVIEWED</b> 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, 03/10/21, 04/14/21	<b>APPROVAL DATE</b> April 14, 2021	<b>EFFECTIVE DATE</b> April 30, 2021	<b>COMMITTEE APPROVAL DATES</b> (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, 03/10/21, 04/14/21	
<b>PRIMARY BUSINESS OWNER:</b> UM		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>URAC STANDARDS</b> HUM 1	<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>	
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> Commercial, Exchange, Medicaid	

### I. PURPOSE

To define and describe the accepted indications for 5HT<sub>3</sub> receptor antagonists (Zofran, Granisetron, Anzemet, Aloxi, Akynzeo, Sancuso, Sustol) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

#### A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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
3. 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
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

## B. Antiemesis

1. NOTE: Per NCH policy, generic intravenous Emend (fosaprepitant) + 5HT3 receptor antagonist [e.g., Zofran (ondansetron), Granisetron, or Aloxi (palonosetron)] are preferred over Akynzeo (netupitant-palonosetron), Sancuso (granisetron patch), or Sustol (granisetron extended release) for moderately/highly emetogenic chemotherapy. Exception: Failure/intolerance to any of the above preferred combinations, OR refractory delayed nausea/emesis despite any of the above preferred combinations.
2. Zofran (ondansetron) OR Granisetron may be used prior to the administration of low, moderate, or highly emetogenic chemotherapy.
  - a. The above agents can also be used:
    - i. Before radiation to the upper abdomen or total body irradiation OR
    - ii. Treatment for nausea/vomiting induced by chemotherapy, immunotherapy, oral oncolytic therapy, targeted therapy, and radiation.
3. Aloxi (palonosetron) is being used in any of the following situations:
  - a. Before moderately/highly emetogenic chemotherapy (emetogenicity of agent/regimen is based on the antiemetic practice guideline from NCCN) OR
  - b. Before low or minimal emetic risk chemotherapy in members who failed or are intolerant to or have a contraindication to Zofran (ondansetron) or Granisetron.
4. Akynzeo (netupitant-palonosetron) is being used before moderate/highly emetic risk chemotherapy.
5. Sancuso (granisetron PATCH) is being used before moderate/highly emetogenic risk chemotherapy.
6. Sustol (granisetron extended release) is being used as ONE of the following:
  - a. Before or after highly emetogenic chemotherapy, for example cisplatin or anthracycline and cyclophosphamide combination chemotherapy regimens OR
  - b. 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

- A. Sustol is being used without failure, intolerance, or contraindications to any 5HT3 + Emend (fosaprepitant/aprepitant) combination.
- B. Aloxi and Akynzeo are being used for prevention of radiation induced nausea and vomiting.

- C. Dose exceeds the maximum single dose limits for IV Zofran 16 mg, Oral Zofran 24 mg, Granisetron 2 mg IV/PO, Sancuso 34.3 mg patch, Anzemet 100 mg, Aloxi 0.25 mg IV, Aloxi 0.5 mg PO, Akynzeo 300 mg/0.5 mg (oral) or 235 mg/0.25 mg (IV), and Sustol 10 mg.
- D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

#### IV. MEDICATION MANAGEMENT

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

#### V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

#### VI. ATTACHMENTS

- A. None

#### VII. REFERENCES

- A. Zofran prescribing information. GlaxoSmithKline Research. Triangle Park, NC 2020.
- B. Granisetron prescribing information. Roche Laboratories Inc. Nutley, New Jersey 2019.
- C. Aloxi prescribing information. Eisai Inc. Woodcliff Lake, NJ 2020.
- D. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminister, NJ 2020.
- E. Sustol prescribing information. Heron Therapeutics. Redwood City, CA 2017.
- F. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ 2020.
- G. Clinical Pharmacology Elsevier Gold Standard 2021.
- H. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.
- K. 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.
- L. Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. Journal of Clinical Oncology 2017 35:28, 3240-3261.