



Policy #UM ONC_1038 PROPRIETARY & CONFIDENTIAL

POLICY NUMBER UM ONC_1038	SUBJECT Emend [™] (Aprepitant oral or Fosaprepitant), Cinvanti (aprepitant injection) and Varubi [™] (rolapitant oral/injection)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 01/12/11, 03/08/12, 10/16/13, 11/12/14, 12/17/15, 05/24/16, 03/04/17, 05/10/17, 01/19/18, 02/14/18, 02/13/19, 12/11/19, 02/12/20	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 01/12/11, 03/08/12, 10/16/13, 11/12/14, 12/17/15, 05/24/16, 03/04/17, 05/10/17, 01/19/18, 02/14/18, 02/13/19, 12/11/19, 02/12/20	
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 Oncology	

I. PURPOSE

To define and describe the accepted indications for Emend (aprepitant oral or fosaprepitant), Cinvanti (aprepitant injection), or Varubi (rolapitant oral/injection) 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: <u>http://pathways.newcenturyhealth.com</u> **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. Emend (aprepitant oral or fosaprepitant), Cinvanti (aprepitant injection), or Varubi (rolapitant oral/injection) is being used in combination with dexamethasone and a serotonin antagonist before chemotherapy:
 - i. Before moderately/highly emetic risk chemotherapy based on the antiemetic practice guideline from NCCN **OR**



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ii. Before low or minimal emetic risk chemotherapy in members who failed, intolerant, or has a contraindication to Zofran (ondansetron) **OR** Kytril (granisetron).

III. EXCLUSION CRITERIA

- 1. Emend, Cinvanti, or Varubi is not to be used for the treatment of established nausea and vomiting.
- 2. Emend, Cinvanti, or Varubi is not used in conjunction with a 5HT₃ antagonists (i.e. ondansetron) and dexamethasone.
- 3. Fosaprepitant (IV aprepitant) is being used in combination or failure with oral/injectable aprepitant.
- 4. Varubi (rolapitant oral/injection) is being used in patients with severe hepatic impairment (Child-Pugh class C) or with CYP2D6 substrates with a narrow therapeutic index such as thioridazine and pimozide.
- 5. Dosing exceeds the single dose limit of aprepitant oral 125 mg and fosaprepitant 150 mg or rolapitant 180 mg and aprepitant injection 130 mg.
- 6. Emend or Cinvanti is being used concomitantly with pimozide, thioridiazine, terfenadine, astemizole, or cisapride.
- 7. 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 UM Department
- 2. Final Approval UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

- 1. Cinvanti prescribing information. Heron Therapeutics, Inc., San Diego, CA. 2019.
- 2. Emend prescribing information. Merck & Co, Inc. Whitehouse Station, NJ. 202019.
- 3. Rolapitant prescribing information. TESARO, Inc. 1000 Winter St., Waltham, MA. 2018.
- 4. Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Focused Guideline Update. J Clin Oncol. 2015 Nov 2. pii: JCO.2015.64.3635.
- 5. Clinical Pharmacology Elsevier Gold Standard. 2020.
- 6. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- 7. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- 8. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.