POLICY NUMBER
UM_1038

SUBJECT
Emend™ (Aprepitant or Fosaprepitant) and Varubi™ (rolapitant)

DEPT/PROGRAM
UM Dept

DATE REVIEWED
01/12/11, 03/08/12, 10/16/13, 11/12/14, 12/17/15, 5/23/16, 3/4/17

APPROVAL DATE
3/8/17

EFFECTIVE DATE
3/8/17

REVISION DATES (latest version listed last)
1/12/11, 03/08/12, 10/16/13, 11/12/14, 12/17/15, 5/24/16

PRIMARY BUSINESS OWNER:
Dr. Andrew Hertler

COMMITTEE/BOARD APPROVAL
Utilization Management Committee

URAC STANDARDS

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 or fosaprepitant) and Varubi™ usage in cancer supportive care.

II. DEFINITIONS

**Emend (aprepitant or fosaprepitant):** is a highly selective substance P neurokinin 1 (NK1) receptor antagonist. Emend inhibits emesis via central actions; it crosses the blood brain barrier and occupies brain NK₁ receptors. Fosaprepitant is a prodrug that is converted to aprepitant.

**Varubi (rolapitant):** prevents delayed nausea and vomiting associated with emetogenic chemotherapy. It does this as competitive and selective antagonist inhibiting the substance P/neurokinin 1 (NK1) receptor.

Emend (aprepitant or fosaprepitant) has FDA approved indication as an adjunct in combination with other antiemetic agents to help prevent acute and delayed nausea and vomiting due to highly and moderately emetogenic chemotherapy. Emend (aprepitant) is FDA approved in adults for the prevention of postoperative nausea and vomiting.

Varubi (rolapitant) is available in 90 mg oral tablets.

Emend is available as Aprepitant in 40 mg, 80 mg, and 125 mg capsules and oral suspension.

Emend is available as Fosaprepitant 150 mg vial.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health may be deemed as not approvable and therefore not
reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

**Inclusion Criteria:** Emend (aprepitant or fosapreptan) may be considered medically necessary when ALL of the following selection criteria is met:

1. **Antiemesis**
   a. Emend (aprepitant or fosapreptan) or Varubi (rolapitant) is being used in combination with dexamethasone and a serotonin antagonist before chemotherapy (for oral aprepitant or rolapitant/IV fosapreptan) or after chemotherapy (for oral apreptan) for the following:
      i. Before moderately/highly emetic risk chemotherapy based on the antiemetic practice guideline from NCCN OR
      ii. Before low or minimal emetic risk chemotherapy in members who failed, intolerant, or has a contraindication to Zofran (ondansetron) OR Kytril (granisetron).

**Exclusion Criteria:** Emend is not considered medically necessary if:

1. Emend is not to be used for the treatment of established nausea and vomiting.
2. Emend is not used in conjunction with a 5HT₃ antagonists (i.e. ondansetron) and dexamethasone.
3. Fosapreptan (IV apreptan) 150 mg is being used in combination with oral apreptan.
4. Arubi (rolapitant) is being used in patients with severe hepatic impairment (Child-Pugh class C).
5. Dosing exceeds the single dose limit of apreptan 125 mg and fosapreptan 150 mg or rolapitant 180 mg.
6. Emend is being used concomitantly with pimozide, terfenadine, astemizole, or cisapride.
7. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

**IV. PROCEDURE**

Requests for Emend shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosing and Administration**
   a. Fosapreptan (IV apreptan):
      i. **Single dose regimen:** 150 mg IV over 20 to 30 min given 30 min prior to chemotherapy on day 1 only (with no apreptan capsules given on days 2 or 3).
   b. Oral apreptan (three day dosing regimen): 125 mg on day 1 and 80 mg on days 2 and 3
   c. Varubi (rolapitant): 180 mg by mouth 1 to 2 hours prior to starting chemotherapy treatment.
d. Fosaprepitant, aprepitant, or rolapitant is used concurrently with a 5HT₃ antagonists (i.e. Ondansetron) and Dexamethasone.

2. Dosage Adjustments:
   - Varubi (rolapitant)-Hepatic, severe impairment (Child-Pugh class C): Avoid use

3. Monitoring
   a. Fluid and electrolyte status in member with significant diarrhea.
   b. Monitor vital signs and hepatic enzymes in symptomatic member.
   c. Emend is a dose-dependent inhibitor of cytochrome P450 isoenzyme 3A4 (CYP3A4). Emend should not be used concurrently with pimozide, terfenadine, astemizole, or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions.

V. APPROVAL AUTHORITY
   1. Review – UM Department
   2. Final Approval – UM Committee

VI. ATTACHMENTS

VII. REFERENCES
2. Rolapitant prescribing information.