Clinical Policy: Rolapitant (Varubi)

Reference Number: PA.CP.PMN.102
Effective Date: 02.01.17
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Revision Log

Description
Rolapitant (Varubi™) is a substance P/neurokinin 1 (NK1) receptor antagonist.

FDA Approved Indication(s)
Varubi is indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness that Varubi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prevention of Delayed Nausea/Vomiting Associated with Emetogenic Cancer Chemotherapy (must meet all)**:**

1. Member is scheduled to receive moderately to highly emetogenic cancer chemotherapy;
2. Failure of a trial of aprepitant (Emend) unless contraindicated or clinically significant adverse effects are experienced;
   **PA is required for aprepitant*
3. Varubi is prescribed in combination with a serotonin ($5\text{-}HT_3$) receptor antagonist (*ondansetron or granisetron is preferred*) and dexamethasone;
4. Dose does not exceed 180 mg/2 weeks (2 tablets/2 weeks).

Approval duration: projected duration of chemotherapy

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Prevention of Delayed Nausea/Vomiting Associated with Emetogenic Cancer Chemotherapy (must meet all)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member continues to receive moderately to highly emetogenic cancer chemotherapy;

4. Varubi is prescribed in combination with a 5-HT3 receptor antagonist and dexamethasone;
5. If request is for a dose increase, new dose does not exceed 180 mg/2 weeks (2 tablets/2 weeks).

Approval duration: projected duration of chemotherapy

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aprepitant (Emend®)	125 mg PO on day 1 and 90 mg PO on days 2 and 3	125 mg/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: ASCO and NCCN Recommendations for NK1 Receptor Antagonists in Oncology

- Minimal emetic risk chemotherapy: No routine prophylaxis is recommended.
- Low emetic risk chemotherapy: NK1 receptor antagonists are not included in antiemetic recommendations. Instead, options include dexamethasone (recommended by both ASCO and NCCN) or metoclopramide, prochlorperazine, or a 5-HT_3 receptor antagonist (recommended by NCCN only).
- Moderate emetic risk chemotherapy: NK1 receptors may be used in combination with 5-HT_3 receptor antagonists and dexamethasone.
  - Examples of moderate emetic risk chemotherapy: azacitidine, alemtuzumab, bendamustine, carboplatin, clofarabine, cyclophosphamide < 1,500 mg/m^2, cytarabine

< 1,000 mg/m^2, daunorubicin, doxorubicin, epirubicin, idarubicin, ifosfamide, irinotecan, oxaliplatin

- High emetic risk chemotherapy: NK1 receptors are recommended for use in combination with 5-HT$_3$ receptor antagonists and dexamethasone.
  - Examples of high emetic risk chemotherapy: carmustine, cisplatin, cyclophosphamide ≥ 1,500 mg/m^2, dacarbazine, dactinomycin, mechlorethamine, streptozocin.

V. References

1. Varubi Prescribing Information. Waltham, MA: Tesaro, Inc.; October 2017. Available at: www.varubi.com. Accessed November 20, 2017.
2. Basch E, Prestrud AA, Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2011; 29(31): 4189-4198.
3. Antiemesis (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed November 20, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date