Clinical Policy: Rolapitant (Varubi)

Reference Number: CP.PMN.102
Effective Date: 02.01.17
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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-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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid 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
Policy created.	12.16	02.17
1Q18 annual review: - Added trial of aprepitant (Emend) since it's generically available. - Added Medicaid line of business as new criteria References reviewed and updated.	11.20.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.
Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.