CENTENE Corporation

Clinical Policy: Rolapitant (Varubi)

Reference Number: CP.PMN.102
Effective Date: 02.01.17
Last Review Date: 02.19
Line of Business: HIM*, Medicaid

Coding Implications
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 (NK_1) receptor antagonist.

**For Health Insurance Marketplace (HIM), if request is through the pharmacy benefit, the intravenous formulation of Varubi is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

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 (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 Nausea and Vomiting Associated with Cancer Chemotherapy (must meet all)**:**

1. Prescribed for the prevention of chemotherapy-induced nausea/vomiting;
2. Age ≥ 18 years;
3. Member is scheduled to receive moderately to highly emetogenic cancer chemotherapy (*see Appendix D*);
4. Failure of aprepitant, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for aprepitant*
5. Prescribed in combination with a serotonin (5-HT_3) receptor antagonist (*ondansetron is preferred*) and dexamethasone;
6. Dose does not exceed:
   a. Oral: 180 mg (2 tablets) every 2 weeks;
   b. IV: 166.5 mg (1 vial) once every 2 weeks.

Approval duration:
Medicaid – Projected duration of chemotherapy

HIM – Projected duration of chemotherapy for tablets (*refer to HIM.PA.103 for intravenous formulation*)

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 Nausea and Vomiting Associated with 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 (*see Appendix D*);
4. Prescribed in combination with a 5-HT_3 receptor antagonist (*ondansetron is preferred*) and dexamethasone;
5. If request is for a dose increase, new dose does not exceed:
   a. Oral: 180 mg (2 tablets) every 2 weeks;
   b. IV: 166.5 mg (1 vial) once every 2 weeks.

Approval duration:
Medicaid – Projected duration of chemotherapy
HIM – Projected duration of chemotherapy for tablets (*refer to HIM.PA.103 for intravenous formulation*)

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
5-HT_3: serotonin 5-hydroxytryptamine, type 3
FDA: Food and Drug Administration

CENTENE Corporation

NCCN: National Comprehensive Cancer Network

NK_1: neurokinin 1

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 then 80 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: Contraindications/Boxed Warnings
- Contraindication(s):
  - Known hypersensitivity to any component of this drug, including soybean oil
  - CYP2D6 substrates with a narrow therapeutic index (e.g., thioridazine and pimozide)
- Boxed warning(s): none reported

Appendix D: American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) Recommendations in Oncology
- Minimal emetic risk chemotherapy: No routine prophylaxis is recommended.
- Low emetic risk chemotherapy: Recommended options include dexamethasone (recommended by both ASCO and NCCN) or metoclopramide, prochlorperazine, or a 5-HT_3 receptor antagonist (recommended by NCCN only). NK_1 receptor antagonists are not included in low risk antiemetic recommendations.
- Moderate emetic risk chemotherapy: 5-HT_3 receptor antagonists and dexamethasone may be used in combination and with or without NK_1 receptor antagonists. Olanzapine may also be used in combination with palonosetron 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: NK_1 receptor antagonists are recommended for use in combination with 5-HT_3 receptor antagonists and dexamethasone. Olanzapine may also be used in combination with 5-HT_3 receptor antagonists, dexamethasone, and/or NK_1 receptor antagonists.
  - Examples of high emetic risk chemotherapy: carmustine, cisplatin, cyclophosphamide $\geq 1,500$ mg/m^2, dacarbazine, dactinomycin, mechlorethamine, streptozocin
- Breakthrough emesis: Per NCCN, an agent from a different drug class is recommended to be added to the current antiemetic regimen. Drug classes include atypical antipsychotics (olanzapine), benzodiazepines (lorazepam), cannabinoids (dronabinol, nabilone), phenothiazines (prochlorperazine, promethazine), 5-HT_3 receptor antagonists (dolasetron, ondansetron, granisetron), steroids (dexamethasone), or (haloperidol, metoclopramide,

scopolamine). An NK_1 receptor antagonist may be added to the prophylaxis regimen of the next chemotherapy cycle if not previously included.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prevention of chemotherapy-induced nausea and vomiting	180 mg PO or 166.5 mg IV as a single dose prior to the initiation of each chemotherapy, but at no less than 2 week intervals	180 mg (PO) or 166.5 mg (IV)/2 weeks

VI. Product Availability

- Tablets: 90 mg
- Single-dose vial, injectable emulsion: 166.5 mg/92.5 mL (1.8 mg/mL)

VII. References

1. Varubi Prescribing Information. Waltham, MA: Tesaro, Inc.; March 2018. Available at: www.varubirx.com. Accessed October 30, 2018.
2. Hesketh, PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol 2017: JCO2017744789.
3. National Comprehensive Cancer Network. Antiemesis Version 3.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed October 30, 2018.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9464	Injection, rolapitant, 0.5 mg
J8670	Rolapitant, oral, 1 mg

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
1Q 2019 annual review: added IV formulation; added requirement that Varubi is being prescribed for chemo-induced N/V; added age requirement; removed granisetron as a preferred agent per formulary; references reviewed and updated.	10.30.18	02.19

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.
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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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