

Clinical Policy: Rolapitant (Varubi)

Reference Number: CP.PMN.102

Effective Date: 02.01.17

Last Review Date: 02.21

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 (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 (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. Member meets one of the following (a or b):
 - a. Failure of aprepitant, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for aprepitant*
 - b. Request is for Stage IV or metastatic cancer for a State with regulations against step therapy in advanced oncology settings (*see Appendix E*);
5. Prescribed in combination with a serotonin (5-HT₃) 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: 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.PA.154 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-HT₃ 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: 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.PA.154 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.PA.154 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-HT₃: serotonin 5-hydroxytryptamine,
type 3

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer
Network

NK₁: 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)
 - Pediatric patients less than 2 years of age due to irreversible impairment of sexual development and fertility in juvenile rats
- 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-HT₃ receptor antagonist (recommended by NCCN only). NK₁ receptor antagonists are not included in low risk antiemetic recommendations.
- Moderate emetic risk chemotherapy: 5-HT₃ receptor antagonists and dexamethasone may be used in combination and with or without NK₁ 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/m², cytarabine < 1,000 mg/m², daunorubicin, doxorubicin, epirubicin, idarubicin, ifosfamide, irinotecan, oxaliplatin
- High emetic risk chemotherapy: NK₁ receptor antagonists are recommended for use in combination with 5-HT₃ receptor antagonists and dexamethasone. Olanzapine may also be used in combination with 5-HT₃ receptor antagonists, dexamethasone, and/or NK₁ receptor antagonists.
 - Examples of high emetic risk chemotherapy: carmustine, cisplatin, cyclophosphamide ≥ 1,500 mg/m², 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-HT₃ receptor antagonists (dolasetron, ondansetron, granisetron), steroids (dexamethasone), or (haloperidol, metoclopramide, scopolamine). An NK₁ receptor antagonist may be added to the prophylaxis regimen of the next chemotherapy cycle if not previously included.

Appendix E: States with Regulations against Redirections in Stage IV or Metastatic Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
LA	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if “clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
OH	Yes	<i>*Applies to Commercial and HIM requests only*</i> For stage 4 metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

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 <i>Administer in combination with dexamethasone and a 5-HT₃ receptor antagonist</i>	180 mg (PO) or 166.5 mg (IV)/2 weeks

VI. Product Availability

- Tablet: 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.; August 2020. Available at: www.varubirx.com. Accessed November 13, 2020.
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 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 13, 2020.

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.

HCPSC Codes	Description
J2797	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
1Q 2020 annual review: no significant changes; references reviewed and updated.	01.22.20	02.20
1Q 2021 annual review: no significant changes; updated contraindications and dosing information per PI; references to HIM.PHAR.21 revised to HIM.PA.154; updated HCPCS code; references reviewed and updated.	11.13.20	02.21
Added allowance for bypassing redirection if state regulations do not allow step therapy in Stage IV or metastatic cancer settings with additional details in appendix E.	04.27.21	

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.

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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.

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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.

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