Varubi (rolapitant)
Policy Number: C9528-C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
7/1/2017	12/18/2019	12/18/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J2797-injection, rolapitant, 0.5mg J8670-rolapitant, oral, 1mg C9464-injection, rolapitant, 0.5mg Q9981-rolapitant, oral, 1mg	RxPA	Q1 2020 20200122C9528-C

PRODUCTS AFFECTED:
Varubi (rolapitant)

DRUG CLASS:
Anti-Neoplastic Support

ROUTE OF ADMINISTRATION:
Oral or Intravenous

PLACE OF SERVICE:
Oral- Retail Pharmacy, Intravenous- infusion center (buy & bill/specialty pharmacy; not for self-administration)

AVAILABLE DOSAGE FORMS:
Varubi 90mg oral tablets, Varubi 166.5mg /92.5ml Emulsion for injection

FDA-APPROVED USES:
Prophylaxis of chemotherapy-induced nausea and vomiting, in combination with other antiemetic agents; including highly emetogenic chemotherapy.

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
For delayed chemotherapy-induced nausea/vomiting prophylaxis associated with highly emetogenic chemotherapy; for delayed chemotherapy-induced nausea/vomiting prophylaxis associated with moderately emetogenic chemotherapy and combinations of anthracycline

REQUIRED MEDICAL INFORMATION:
A. FOR CHEMOTHERAPY INDUCED NAUSEA/VOMITING PROPHYLAXIS:

1. Documentation of the treatment plan including the names all of chemotherapy agents; frequency; length cycle and duration of therapy
   AND
2. Patient is receiving highly or moderately emetogenic chemotherapy (see HEC/MEC list below);

AND

3. Must be used in combination with a 5-HT3 receptor antagonist such as ondansetron, granisetron, palonosetron, etc.;
   AND
4. Medication will be used in combination with corticosteroid such a dexamethasone, unless documentation of contraindication to dexamethasone is provided
   AND
5. Patient is not on any concurrent CYP2D6-substrates with a narrow therapeutic index (e.g. thioridazine, pimozide, etc
   AND
6. Documentation that the patient has experienced inadequate response or contraindication to aprepitant/ foasaprepitant AND generic oral ondansetron OR generic oral granisetron with dexamethasone

(NOTE: the proper succession for these criteria can be found within compendia monographs, FDA label or NCCN guidelines; IF compendia monographs, FDA label or NCCN guidelines have a formulary/preferred product at therapeutic parity with requested agent a formulary/preferred product should be used first where state regulations allow) Molina reviewers and delegates will comply with all regulations and requirements applicable to the review of the request, providing exception to our standard criteria as may be required under state regulations and requirements.

DURATION OF APPROVAL:
Initial authorization: 3 months (or length of chemotherapy, whichever is shorter) Continuation of Therapy: 3 months (or length of chemotherapy, whichever is shorter)

QUANTITY:
Quantity Limit (max daily dose) [Pharmacy Benefit]: 166.5 mg single dose vial: 1 vial per 14 days
Max Units (per dose and over time) [Medical Benefit]: 166.5 mg on day 1 of chemo every 14 days
Quantity Limit (max daily dose) [Pharmacy Benefit]: 90 mg: 1 vial per 14 days
Max Units (per dose and over time) [Medical Benefit]: 90 mg on day 1 of chemo every 14 days

PRESCRIBER REQUIREMENTS:
No requirements

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:

A. FOR CHEMOTHERAPY INDUCED NAUSEA/VOMITING PROPHYLAXIS:
   1. Member is complaint with medication as evidenced by claim history and chart notes.
      AND
   2. Member is benefiting from the medication as evidenced by recent chart notes.
      AND
   3. Member does not experience side effects from therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
The safety and effectiveness of rolapitant have not been established in pediatric patients (neonates, infants, and children).

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:

APPENDIX:
NCCN & ASCO Antiemetic Guidelines LINK

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Varubi (rolapitant) [prescribing information]. Lake Forest, IL: TerSera Therapeutics LLC; September 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Rolapitant. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org.