Manual Prior Criteria

MISSISSIPPI DIVISION OF MEDICAID

VARUBI® (*rolipitant*) PA CRITERIA:

A substance P/NK1 Receptor Antagonist
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

Diagnosis: _____ ICD-10 code(s) plus description:
_____

Initial request:

Varubi will be approved based on ALL of the following criteria:

☐ Age 18 years or older ***AND***
☐ Documented diagnosis of cancer OR Antineoplastic history
Medication prescribed by or in consultation with an oncologist ***AND***
☐Yes ☐No Chemotherapy regimen includes use of a highly or moderately emetogenic* chemotherapeutic agent ***AND***
☐Yes ☐No History of prior use of preferred combination antiemetic therapy ***AND***
☐Yes ☐No Concurrent use of dexamethasone and 5-HT_3 receptor antagonist per PI (note below specific days for use)

Highly emetogenic chemotherapy*
Usual Dose:

- Day 1
  Varubi 180 mg- two (90mg) tablets one to two hours prior to initiation of chemotherapy
  Dexamethasone 20 mg 30 minutes prior to chemotherapy
  5-HT_3 receptor antagonist (see appropriate dosing information per PI)
- Day 2, 3 and 4
  Varubi: None
  Dexamethasone 8 mg twice daily
  5-HT_3 receptor antagonist: None

Moderately emetogenic chemotherapy*

- Day 1
  Varubi 180 mg- two (90 mg) tablets one to two hours prior to initiation of chemotherapy.
  Dexamethasone: 20 mg 30 minutes prior to initiation of chemotherapy.
  5-HT_3 receptor antagonist (see appropriate dosing information per PI)
- Day 2, 3 and 4
  Varubi: None
  Dexamethasone: None
  5-HT_3 receptor antagonist (see appropriate dosing information per PI)

Initial authorization will be issued for 6 months.

Reauthorization:

Varubi will be approved based on the following criteria:

- Documentation of positive clinical response to Varubi.
- Chemotherapy regimen includes an agent of highly or moderately emetogenic chemotherapeutic agent.

***Class of emetogenic therapy as defined by FDA label, compendia or NCCN guidelines**

Addition information to consider:

Varubi may interact with CYP2D6 substrates with a narrow therapeutic index. The inhibitory effect of a single dose of Varubi on CYP2D6 lasts at least 7 days and may last longer.

Consider possible interactions with BCRP and P-gp substrates with a narrow therapeutic index, and with strong CYP3A4 inducers.

Quantity Limits:
2 tablets [180mg (90mg / tab)] per chemotherapy session.
4 tablets/28days

Per Package Insert: Administer VARUBI prior to the initiation of each chemotherapy cycle, but at no less than 2 week intervals.

How Supplied:
VARUBI tablets:

Each tablet contains 90 mg rolapitant. VARUBI tablets are packaged in an Aclar blister shell with aluminum foil backing and supplied as follows:

- A single dose child-resistant wallet (2 tablets as one set of twinned blisters)

Injectable emulsion: 166.5 mg/92.5 mL (1.8 mg/mL) of rolapitant in a single-dose vial

- The recommended dosage is 166.5 mg administered as an intravenous infusion over 30 minutes. (injection available only via medical benefit)