Varubi

Description

Varubi (rolapitant)

Background
Varubi is a medicine called an “antiemetic.” Antiemetic drugs are medications used to treat nausea and vomiting. Varubi is used in combination with other antiemetic drugs to prevent delayed-phase chemotherapy-induced nausea and vomiting. Delayed-phase chemotherapy-induced nausea and vomiting is when cancer patients experience nausea and vomiting one to five days after starting anti-cancer medication (chemotherapy). Varubi is an oral tablet that works by blocking substance P/neurokinin-1 (NK1) receptors, which play an important role in nausea and vomiting (1).

Regulatory Status
FDA-approved indication: 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 (2).

Varubi is contraindicated in patients receiving the CYP2D6 substrate thioridazine. Significant increases in plasma concentrations of thioridazine may result in QT prolongation and Torsades de Pointes (2).

There may be serious interactions if Varubi is used in combination with CYP2D6 substrates with a narrow therapeutic index such as pimozide. Varubi moderately inhibits CYP2D6 for at least 7
days. If this combination cannot be avoided, monitor closely for QT prolongation and other adverse events (2).

Avoid the chronic use of strong CYP3A4 inducers (e.g., rifampin) in combination with Varubi. They can significantly reduce the plasma concentrations of Varubi and decrease its efficacy (2).

Avoid use of Varubi in severe hepatic impairment (Child-Pugh Class C) since there is no clinical or pharmacokinetic data on this population. If the use cannot be avoided, monitor for adverse events (2).

Safety and effectiveness of Varubi in patients under the age of 18 has not been established (2).

Related policies
Akynzeo, Emend

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Varubi in combination with other antiemetic agents may be considered medically necessary for patients 18 years of age and older to prevent delayed nausea and vomiting associated with initial and repeat courses of moderately or highly emetogenic cancer chemotherapy; must be administered with dexamethasone and a 5-HT3 receptor antagonist and in the absence of severe hepatic impairment (Child-Pugh Class C).

Varubi is considered investigational in patients that are less than 18 years of age and in patients with any other diagnosis.

Prior-Approval Requirements

Age: 18 years of age or older

Diagnosis

Patient must have the following:

Prevention of delayed nausea and vomiting
AND ALL of the following:
1. Undergoing chemotherapy for cancer
2. Administered with dexamethasone and a 5-HT3 receptor antagonist
3. Absence of severe hepatic impairment (Child-Pugh Class C)

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
Quantity 2 capsules
Duration 30 days

Prior - Approval Limits
Quantity 12 capsules
Duration 3 months

Prior – Approval Renewal Limits
Quantity 12 capsules
Duration 3 months

Rationale

Summary
Varubi is indicated for the prevention of delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy. Delayed-phase chemotherapy-induced nausea and vomiting is when cancer patients experience nausea and vomiting one to five days after starting anti-cancer medication. There are no adequate and well-controlled studies to document the safety and efficacy of Varubi in pediatric patients (2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Varubi while maintaining optimal therapeutic outcomes.

References
   http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm460838.htm

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2015</td>
<td>New addition to PA</td>
</tr>
<tr>
<td>December 2015</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2015 and is effective January 1, 2016.

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