Protocol for Varubi® (rolapitant)

Approved July 2020

Background:
Varubi is a substance P/neurokinin (NK1) receptor antagonist indicated in the 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.

Criteria for approval:

1. Patient is ≥ 18 years of age or older
2. Medication is for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy or as recommended by the National Comprehensive Cancer Network
3. Patient is using Varubi in combination with a corticosteroid such as dexamethasone and a 5-HT3 receptor antagonist (for example, ondansetron, granisetron, dolasetron) or as recommended by the National Comprehensive Cancer Network
4. Patient does not have any contraindications to therapy (patient is not taking CYP2D6 substrates with a narrow therapeutic index [for example. thioridazine and pimozide])
5. Patient has experienced a therapeutic failure or inadequate response to generic oral antagonists of human substance P/neurokinin 1 (NK1) receptors (for example, aprepitant or fosaprepitant), or has contraindications to all
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer reviewed evidence

Initial Approval Duration: 3 months

Continuation of therapy:

1. Patient is responding positively to therapy
2. Patient continues to receive moderately to highly emetogenic cancer chemotherapy
3. Patient is using Varubi in combination with a corticosteroid such as dexamethasone
4. Patient is using Varubi in combination with a 5-HT3 receptor antagonist (e.g.
5. ondansetron, granisetron, dolasetron)
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer reviewed evidence

Renewal Approval Duration: 3 months

References:

1. Varubi [package insert]. TESARO Inc. 1000 Winter St., #3300, Waltham, MA 02451; September 2015
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2018. Updated periodically
3. Karthaus M, et al. Neurokinin-1 receptor antagonists: review of their role for the prevention of chemotherapy-induced nausea and vomiting in adults. Expert Review of Clinical Pharmacology 2019,Vol. 12, No.7, 661-680
4. NCCN Drugs & Biologics Compendium™. National Comprehensive Cancer Network. 2020. Available at: http://www.nccn.org/index.asp. NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2020. National Comprehensive Cancer Network, 2020. Accessed March 2020.