Policy Title:	Varubi (rolapitant), Cinvanti (aprepitant), Akynzeo (fosnetupitant/palonosetron) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	4/10/2019, 6/14/2019, 12/20/2019		
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Purpose: To support safe, effective and appropriate use of Varubi (rolapitant), Cinvanti (aprepitant), and Akynzeo (fosnetupitant/palonosetron).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Varubi (rolapitant), Cinvanti (aprepitant), and Akynzeo (fosnetupitant/palonosetron) are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Varubi (rolapitant), Cinvanti (aprepitant), and Akynzeo (fosnetupitant/palonosetron) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria Coverage For Medicaid and Exchange:

Varubi (rolapitant) and Cinvanti (aprepitant):

- Patient age of 18 years or older; AND
- Being used for the prevention of Chemotherapy Induced Nausea and Vomiting (CINV)
- Patient is receiving highly or moderately emetogenic chemotherapy as listed in the most recent NCCN Guidelines; AND
- Must be used in combination with a 5-HT_3 receptor antagonist such as ondansetron, granisetron, palonosetron, etc.; AND
- Must be used in combination with a corticosteroid such as dexamethasone; AND
- Patient is not on any concurrent CYP2D6-substrates with a narrow therapeutic index (e.g. thioridazine, pimozide, etc); OR

Akynzeo (fosnetupitant/palonosetron):

- Patient age of 18 years or older; AND
- Being used for the prevention of Chemotherapy Induced Nausea and Vomiting (CINV); AND
- Patient is receiving highly emetogenic chemotherapy (HEC); AND

- Used in combination with dexamethasone; AND
- Patient must have a failure** with another generically available 5-HT_3 receptor antagonist (e.g. ondansetron, granisetron or palonosetron) and NK1 receptor antagonist (e.g. aprepitant, fosaprepitant or rolapitant) while receiving the current chemotherapy regimen; AND

  ** Failure is defined as two or more documented episodes of vomiting attributed to the current chemotherapy regimen
- Akynzeo is NOT covered for:
  - Breakthrough emesis; OR
  - Repeat dosing in multi-day emetogenic chemotherapy regimens; OR
  - CINV related to an anthracycline plus cyclophosphamide chemotherapy regimen.

Initial Criteria Coverage For Medicare-Medicaid Plan (MMP):

Varubi (rolapitant) and Cinvanti (aprepitant):

- Patient age of 18 years or older; AND
- Being used for the prevention of Chemotherapy Induced Nausea and Vomiting (CINV)
- Patient is receiving highly or moderately emetogenic chemotherapy as listed in the most recent NCCN Guidelines; AND
- Must be used in combination with a 5-HT_3 receptor antagonist such as ondansetron, granisetron, palonosetron, etc.; AND
- Must be used in combination with a corticosteroid such as dexamethasone; AND
- Patient is not on any concurrent CYP2D6-substrates with a narrow therapeutic index (e.g. thioridazine, pimozide, etc).

Akynzeo (fosnetupitant/palonosetron):

- Patient age of 18 years or older; AND
- Being used for the prevention of Chemotherapy Induced Nausea and Vomiting (CINV); AND
- Patient is receiving highly emetogenic chemotherapy (HEC); AND
- Used in combination with dexamethasone; AND
- Akynzeo is NOT covered for:
  - Breakthrough emesis; OR
  - Repeat dosing in multi-day emetogenic chemotherapy regimens; OR
  - CINV related to an anthracycline plus cyclophosphamide chemotherapy regimen.

Renewal coverage:

- Patient continues to meet initial criteria; AND
- Patient is tolerating treatment; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: reactions related to drug interactions, severe neutropenia, etc

Drug	Dose	Billable unit (BU)
Varubi (rolapitant)	• 166.5 mg IV Day 1, given within 2 hours prior to chemotherapy (single dose regimen) and at no less than 2 week intervals.	• 0.5mg = 1 BU (333 BU per dose)
Cinvanti (aprepitant)	• HEC (Single Dose Regimen): 130 mg IV Day 1, given 30 minutes prior to chemotherapy • MEC (3-Day Regimen with oral aprepitant): 100 mg IV Day 1, given 30 minutes prior to chemo followed by oral apprepitant 80mg on Day 2-3.	• 1mg = 1 BU (130 BU per dose)
Akynzeo (fosnetupitant/palonosetron)	• Administer the contents of 1 vial, intravenously, approximately 30 minutes prior to the start of chemotherapy	• 1 vial = 1 BU

HEC = Highly Emetogenic Chemotherapy
MEC = Moderately Emetogenic Chemotherapy

Coverage durations:

- Initial & Renewal coverage = 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Investigational Use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg.
J2797	Injection, rolapitant, 0.5 mg.
J0185	Injection, aprepitant, 1 mg

References:

1. Varubi [package insert]. Waltham, MA; Tesaro, Inc; October 2017. Accessed January 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. January 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 2.2017. National Comprehensive Cancer Network, 2017. 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. Accessed January 2018.
4. Cinvanti [package insert]. San Diego, CA; Heron Therapeutics; November 2017. Accessed January 2018.
5. Akynzeo [package insert]. Helsinn Therapeutics (U.S.), Inc., Iselin, NJ, under license of Helsinn Healthcare SA, Switzerland. April 2018. Accessed April 2018.