

# Antiemetics

# **PRODUCTS AFFECTED**

Akynzeo (fosnetupitant/palonosetron; netupitatnt/palonosetron), Aloxi (palonosetron), Anzemet (dolasetron), Aponvie (aprepitant), aprepitant, Cinvanti (aprepitant), Emend (aprepitant/fosaprepitant), fosaprepitant, granisetron, palonosetron, Sancuso (granisetron) patch, Sustol (granisetron) PFS, Varubi (rolapitant)

# **COVERAGE POLICY**

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

# 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.

### **DIAGNOSIS:**

Chemotherapy-induced nausea/vomiting (CINV) prophylaxis, Post-operative nausea/vomiting (PONV) prophylaxis

### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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- A. CHEMOTHERAPY INDUCED NAUSEA/VOMITING PROPHYLAXIS:
  - Documentation of the treatment plan including the names all of chemotherapy and or radiation agents, frequency, length, cycle and duration of therapy AND
  - Product being requested has an FDA labeled indication or compendia supported use for diagnosis, age, and dose AND
  - 3. Prescriber attests that medication will be used in combination (when indicated per FDA label or guideline) with other antiemetic agents (5HT3 antagonist) OR used in combination with corticosteroid such a dexamethasone, unless documentation of contraindication to dexamethasone is provided, per FDA label or NCCN guideline AND
  - Prescriber attests that medication will NOT be used with additional agents if FDA label or guideline does not support concurrent therapy AND
  - 5. Prescriber attests to review of concurrent medication therapy for drug-drug interactions AND
  - FOR ALOXI, ANZEMET ONLY: FOR HIGH EMETIC IV CHEMOTHERAPY AND CONCURRENTLY RECEIVING APREPITANT OR FOSAPREPITANT ONLY: Documentation of trial and failure or labeled contraindication of preferred serotonin-receptor antagonists (ondansetron and granisetron) AND
  - FOR SANCUSO AND SUSTOL: Documentation of trial and failure or labeled contraindication of preferred serotonin-receptor antagonist [ondansetron and granisetron (any dosage form)] AND
  - 8. FOR VARUBI ONLY: (a)Documentation that the member has experienced inadequate response or contraindication to aprepitant/ fosaprepitant AND generic oral ondansetron OR generic oral granisetron with dexamethasone AND (b) Prescriber attests that Varubi (rolapitant) will not be administered any less than a 2-week interval between doses

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.

- B. POST-OPERATIVE NAUSEA/VOMITING PROPHYLAXIS:
  - 1. Documentation of expected surgery date (within the next 30 days) AND
  - 2. Product being requested has an FDA labeled indication or compendia supported use for diagnosis, age and dose AND
  - 3. Prescriber attestation to a historical trial and failure or labeled contraindication to preferred serotonin-receptor antagonists (ondansetron and IV granisetron)

# CONTINUATION OF THERAPY:

A. CHEMOTHERAPY INDUCED NAUSEA/VOMITING PROPHYLAXIS:

- 1. Documentation of continuation of chemotherapy requiring antiemetics. AND
- 2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity or development of contraindications (e.g., hypersensitivity reactions, serotonin syndrome, etc.)

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B. POST-OPERATIVE NAUSEA/VOMITING PROPHYLAXIS: N/A Must submit new request

### **DURATION OF APPROVAL:**

Post-Operative nausea/vomiting prophylaxis: Initial authorization: One-time authorization, Continuation of Therapy: N/A

Chemotherapy Induced Nausea/Vomiting Prophylaxis: Initial authorization: 3 months (or length of chemotherapy or radiation therapy, whichever is shorter), Continuation of Therapy: 6 months (or length of chemotherapy or radiation, whichever is shorter)

### PRESCRIBER REQUIREMENTS:

No requirements

### AGE RESTRICTIONS:

Akynzeo (fosnetupitant/palonosetron; netupitant/palonosetron): 18 years of age or older Aloxi (palonosetron): Highly and moderately emetogenic cancer chemotherapy (HEC, MEC): 1 month of age and older; Postoperative nausea and vomiting (PONV) for up to 24 hours following surgery: 18 years and older Anzemet (dolasetron): 2 years of age and older Aponvie (aprepitant): 18 years of age and older Cinvanti: 18 years of age or older Emend oral suspension or injection: 6 months of age or older Emend capsules: 12 years of age or older

Granisetron: 2 years of age and older

Sancuso: 18 years of age and older

Sustol (granisetron ER inj): 18 years of age and older

Varubi (rolapitant): 18 years of age and older

# QUANTITY:

Akynzeo (fosnetupitant/palonosteron; netupitant/palonosetron): Maximum 1 day per cycle of chemotherapy Aloxi (palonosetron): FOR CINV PROPHYLAXIS: Adults: (0.25mg/5ml) 1 vial per 7-day supply or 1 capsule one hour prior to the start of chemotherapy, Pediatrics <17 years of age: 20 mcg/kg IV single dose up to a maximum dose of 1500mcg; FOR PONV: 0.075mg approved ONCE per authorization Anzemet (dolasetron): Adults – 100mg given within 1 hour before chemotherapy; Pediatric patients 2-16: 1.8 mg/kg given within 1 hour before chemotherapy up to a maximum of 100mg

Aponvie (aprepitant): 32mg IV injection ONCE per authorization

Cinvanti (aprepitant): 130 mg on Day 1 for HEC and MEC (single-dose regimen), or 100 mg on Day 1 for MEC (3-day regimen).

Emend (aprepitant capsules, oral suspension), Emend (fosaprepitant inj): CINV: oral suspension or capsules: Dose does not exceed 125 mg on Day 1, followed by 80mg on Days 2 and 3 per chemotherapy cycle; injection: 150 mg on Day 1; [Pediatric doses are weight based and should follow FDA label for members 6 months to 12 years of age]

Emend (aprepitant capsules): PONV: Dose does not exceed 40 mg (1 capsule) once.

Granisetron tablets: up to a maximum of 60 tablets/30 days

Sancuso (granisetron patches), Sustol (granisetron ER inj.), and granisetron injection: quantity not to exceed FDA label per indication

Varubi (rolapitant): 180 mg on day 1 of chemo every 14 days

Quantities above the plan limit for chemotherapy induced nausea/vomiting will be approved when ONE of the following is met:

- 1. The member has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month OR
- 2. The member has delayed emesis in highly emetogenic

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chemotherapy OR

- 3. The member has radiation therapy induced nausea and vomiting and radiation treatment that extends beyond 7 days per month OR
- 4. The prescriber has submitted documentation in support of the requested therapeutic use and quantity for the requested medication which has been reviewed and approved by the Clinical Review pharmacist

### PLACE OF ADMINISTRATION:

The recommendation is that oral and transdermal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

### **DRUG INFORMATION**

### **ROUTE OF ADMINISTRATION:**

Oral, Intravenous, Transdermal

### DRUG CLASS:

Antiemetics

### FDA-APPROVED USES:

AKYNZEO (netupitant and palonosetron) capsules is indicated:

In combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

AKYNZEO (fosnetupitant and palonosetron) for injection is indicated:

In combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

Limitations of Use: AKYNZEO for injection and AKYNZEO injection have not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.

ALOXI (palonosetron) indicated in:

Adults for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy (MEC) or (HEC), postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. *Efficacy beyond 24 hours has not been demonstrated* 

Pediatric patients aged 1 month to less than 17 years for prevention of: acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy (HEC)

ANZEMET (dolasetron) is indicated for:

The prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older

APONVIE (aprepitant) is indicated for:

The prevention of postoperative nausea and vomiting (PONV) in adults. Limitations of use: Aponvie has not been studied for treatment of established nausea and vomiting.

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CINVANTI (aprepitant) is indicated:

In adults, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen, and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen.

Limitations of Use: CINVANTI has not been studied for treatment of established nausea and vomiting.

EMEND (aprepitant) for oral suspension is indicated:

In combination with other antiemetic agents, in patients **6 months of age and olde**r for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin or moderately emetogenic cancer chemotherapy (MEC)

EMEND (aprepitant) capsules is indicated:

In combination with other antiemetic agents, in patients **12 years of age and older** for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin or moderately emetogenic cancer chemotherapy (MEC)

*Limitations of Use: EMEND has not been studied for treatment of established nausea and vomiting. Chronic continuous administration of EMEND is not recommended.* 

EMEND (fosaprepitant) for injection is indicated:

In adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin or moderately emetogenic cancer chemotherapy (MEC)

Limitations of use: Emend has not been studied for treatment of established nausea and vomiting.

### GRANISETRON is indicated for:

Prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin, and the prevention and treatment of postoperative nausea and vomiting in adults.

### SANCUSO (granisetron transdermal) is indicated:

For prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days.

SUSTOL (granisetron) ER inj. is indicated:

In combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

VARUBI (rolapitant) 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

# COMPENDIAL APPROVED OFF-LABELED USES: None

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### APPENDIX

### **APPENDIX:**

Antiemetics: ASCO Guideline Update J Clin Oncol 38:2782-2797. © 2020 by American Society of Clinical Oncology

### Emetic Risk of Single Intravenous Antineoplastic Agents in Adults

### Risk Level High (>90%)

Anthracycline/cyclophosphamide combination Carmustine Cyclophosphamide > 1,500 mg/m2

#### Moderate (30%-90%)

Alemtuzumab Arsenic trioxide Azacitidine Bendamustine Busulfan Carboplatin Clofarabine Cyclophosphamide, 1,500mg/m2 Cytarabine 1,000 mg/m2 Daunorubicin Daunorubicin and cytarabine liposome

### Low (10%-30%)

Aflibercept Axicabtagene ciloleucel **Belinostat** Blinatumomab Bortezomib **Brentuximab** Cabazitaxel Carfilzomib Catumaxumab Cetuximab Copanlisib Cytarabine # 1,000 mg/m2 Decitabine Docetaxel Elotuzumab Enfortumab vedotin-ejfv Eribulin Etoposide Fluorouracil Gemcitabine Gemtuzumab ozogamicin Inotuzumab ozogamicin

### Minimal (<10%)

Atezolizumab Avelumab Bevacizumab Bleomycin Cemiplimab Chlorodeoxyadenosine Dacarbazine Mechlorethamine Streptozocin

- Doxorubicin Epirubicin Fam-trastuzumabderuxtecan-nxki Idarubicin Ifosfamide Irinotecan Irinotecan liposomal injection Oxaliplatin Romidepsin Temozolomidea Thiotepab Trabected
- Ixabepilone Methotrexate Mitomycin Mitoxantrone Moxetumomab pasudotox Nab-paclitaxel Necitumumab Nelarabine Paclitaxel Panitumumab Pegylated liposomal doxorubicin Pemetrexed Pertuzumab Tagraxofusp-erzs Temsirolimus Tisagenlecleucel Topotecan Trastuzumab-emtansine Vinflunine

Nivolumab Obinutuzumab Ofatumumab Pembrolizumab Pixantrone Polatuzumab vedotin

Cladribine Daratumumab Durvalumab Emapalumab Fludarabine Ipilimumab

Pralatrexate Ramucirumab Rituximab Trastuzumab Vinblastine Vincristine Vinorelbine

# Emetic Risk of Single, Oral Antineoplastic Agents in Adults

Moderate or high (> 30%) Abemaciclib Lenvatinib Avapritinib Lomustine Bosutinib Midostaurin Cabozantinib Niraparib Ceritinib Procarbazine Ribociclib Crizotinib Cyclophosphamide Rucaparib Enasidenib Selinexor Fedratinib Hexamethylmelamine Temozolomide Imatinib

### Minimal or low (< 30%)

6-Thioguanine Acalabrutinib Afatinib Alectinib Alpelisib Axitinib Bexarotene Brigatinib Capecitabine Chlorambucil Cobimetinib Dabrafenib Dacomitinib Dasatinib Duvelisib Encorafenib Entrectinib Erdafitinib Erlotinib Estramustine Etoposide **Everolimus** Fludarabine Gefitinib Gilteritinib Glasdegib Hydroxyurea Ibrutinib Idelalisib Ivosidenib Ixazomib

TAS-102 (trifluridine-tipiracil) Vinorelbine

Lapatinib Larotrectinib Lenalidomide Lorlatinib Melphalan Methotrexate Neratinib Nilotinib Olaparib Osimertinib Palbociclib Panobinostat Pazopanib Pexidartinib Pomalidomide Ponatinib Regorafenib Ruxolitinib Sonidegib Sorafenib Sunitinib Talazoparib Tazemetostat Tegafur-Uracil Thalidomide Topotecan Trametinib Vandetanib Vemurafenib Venetoclax Vismodegib Vorinostat Zanubrutinib

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# BACKGROUND AND OTHER CONSIDERATIONS

### **BACKGROUND:**

None

### CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of antiemetics are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

Contraindications to Akynzeo (fosnetupitant-palonosetron; netupitant-palonosetron) include: No labeled contraindications

Contraindications to Aloxi (palonosetron) include: Hypersensitivity to palonosetron

Contraindications to Anzemet (dolasetron) include: Patients known to have hypersensitivity to the drug Contraindications to Aponvie (aprepitant) include: Known hypersensitivity to any component of the product, concurrent use with pimozide, avoid concomitant use with strong CYP3A4 inhibitors (ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, nelfinavir) and strong CYP3A4 inducers (rifampin, carbamazepine, phenytoin), avoid use in pregnant women (due to the alcohol content).

Contraindications to Cinvanti (aprepitant) include: Known hypersensitivity to any component of the drug, concurrent use with pimozide, avoid concomitant use with moderate to strong CYP3A4 inhibitors (diltiazem, ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, nelfinavir) and strong CYP3A4 inducers (rifampin, carbamazepine, phenytoin)

Contraindications to Emend (aprepitant, fosaprepitant) include: Known hypersensitivity to any component of the drug, concurrent use with pimozide, avoid concomitant use with moderate to strong CYP3A4 inhibitors (diltiazem, ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, nelfinavir) and strong CYP3A4 inducers (rifampin, carbamazepine, phenytoin)

Contraindications to Granisetron include: Patients with known hypersensitivity to the drug or any of its components

Contraindications to Sancuso (granisetron) include: Known hypersensitivity to granisetron or to any of the components of the transdermal system

Contraindications to Sustol (granisetron) include: Hypersensitivity to granisetron, any of the components of Sustol, or to any of the other 5-HT3 receptor antagonists

Contraindications to Varubi (rolapitant) include: Patients taking CYP2D6 substrates with a narrow therapeutic index (e.g., thioridazine and pimozide), and pediatric patients less than 2 years of age because of irreversible impairment of sexual development and fertility in juvenile rats, avoid in patients who require chronic administration of strong CYP3A4 inducers (e.g., rifampin)

### **OTHER SPECIAL CONSIDERATIONS:**

Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

Emend for oral suspension should be prepared by healthcare provider. Once prepared, it may be administered either by a healthcare provider, patient, or caregiver. Sustol is intended for subcutaneous injection by a health care provider.

### **CODING/BILLING INFORMATION**

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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HCPCS CODE	DESCRIPTION
J1454	Injection, fosnetupitant 235mg/ palonosetron 0.25mg
J2469	Injection, palonosetron, 25mcg
J0185	Injection, aprepitant, 1 mg
J1453	Injection, fosaprepitant, 1 mg
J1456	Injection, fosaprepitant (teva), not therapeutically equivalent to J1453, 1 mg
J3490 (C9145)	Unclassified drug (Aponvie)
J1627	Injection, granisetron, extended-release, 0.1 mg

# AVAILABLE DOSAGE FORMS:

Akynzeo (Ready-to-Use) SOLN 235-0.25MG/20ML Akynzeo (To-be-Diluted) SOLN 235-0.25MG/20ML Akynzeo CAPS 300-0.5MG Akynzeo SOLR 235-0.25MG Aloxi SOLN 0.25MG/5ML Anzemet TABS 100MG Anzemet TABS 50MG Apropitant CAPS 125MG Aprepitant CAPS 40MG Aprepitant CAPS 80 & 125MG Aprepitant CAPS 80 MG Aprepitant MISC 80 & 125MG Cinvanti EMUL 130MG/18ML Emend CAPS 40MG Emend CAPS 80MG Emend SOLR 150MG Emend SUSR 125MG/5ML Emend Tri-Pack CAPS 80 & 125MG Fosaprepitant Dimeglumine SOLR 150MG Granisetron HCI SOLN 1MG/ML Granisetron HCI SOLN 4MG/4ML Granisetron HCI SOLN 4MG/4ML Granisetron HCI SOLN 0.25MG/2ML Palonosetron HCI SOLN 0.25MG/5ML Palonosetron HCI SOSY 0.25MG/5ML Sancuso PTCH 3.1MG/24HR Sustol PRSY 10MG/0.4ML Varubi (180 MG Dose) TBPK 2 x 90MG

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions:	Q1 2024
Required Medical Information	
Continuation of Therapy	
FDA-Approved Uses	
Compendial Approved Off-	
Labeled Uses	
Other Special Considerations	
Available Dosage Forms References	
REVISION- Notable revisions:	Q3 2023
Products Affected	Q3 2023
Age Restrictions	
Quantity	
FDA-Approved Uses	
Contraindications/Exclusions/Discontinuation	
Coding/Billing Information	
Available Dosage Forms	
References	
REVISION- Notable revisions:	Q1 2023
Products Affected	
Diagnosis	
Required Medical Information	
Continuation of Therapy	
Age Restrictions	
Quantity	
FDA-Approved Uses	
Contraindications/Exclusions/Discontinuation	
Other Special Considerations	
Coding/Billing Information	
Available Dosage Forms	
References	Listerial sharpes on file
Q2 2022 Established tracking in new format	Historical changes on file

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