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Policy Number: C20780-A

Antiemetics

PRODUCTS AFFECTED

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

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 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.

A. FOR CHEMOTHERAPY INDUCED NAUSEA/VOMITING PROPHYLAXIS:

1. Documentation of the treatment plan including the names all of chemotherapy and or radiation agents; frequency; length, cycle and duration of therapy

Drug and Biologic Coverage Criteria

- AND
3. Product being requested has an FDA labeled indication or compendia supported use for diagnosis, age, and dose
AND
 4. 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 as dexamethasone, unless documentation of contraindication to dexamethasone is provided, per FDA label or NCCN guideline and 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
 6. 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
 7. 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
AND
 9. FOR PEDIATRIC REQUESTS FOR ALOXI, ANZEMET, EMEND: Documentation of member's current weight (within the last 30 days)

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. FOR 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/VOMITTING (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.)

B. FOR POST-OPERATIVE NAUSEA/VOMITING PROPHYLAXIS: N/A MUST SUBMIT NEW REQUEST

Drug and Biologic Coverage Criteria

DURATION OF APPROVAL:

Post-Operative nausea/vomiting prophylaxis: one-time authorization

All other indications: 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/palonosteron; netupitant/palonosetron): 18 years of age or older

Aloxi (palonosetron): Postoperative nausea and vomiting (PONV) for up to 24 hours following surgery: 18 years and older

Highly and moderately emetogenic cancer chemotherapy (HEC, MEC): 1 month of age and older

Anzemet (dolasetron): 2 years of age and older

Emend oral suspension or injection: 6 months of age or older

Emend capsules: 12 years of age or older

Cinvanti: 18 years of age or older

Granisetron: 2 years of age and older

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

Sancuso: 18 years of age and older

Varubi (rolapitant): 18 years of age and older

Aponvie (aprepitant): 18 years of age and older

QUANTITY:

Akynzeo (fosnetupitant/palonosteron; netupitant/palonosetron): Maximum 1 day per cycle of chemotherapy

Aloxi (palonosetron): FOR CHEMOTHERAPY INDUCED NAUSEA/VOMITING 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 POST-OPERATIVE NAUSEA/VOMITINGPROPHYLAXIS: 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

Emend (aprepitant capsules, oral suspension), Emend (fosaprepitant inj): Prevention of Nausea and Vomiting Associated with Cancer Chemotherapy: 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): Prevention of Postoperative Nausea and Vomiting: Dose does not exceed 40 mg (1 capsule) once.

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).

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

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

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

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

Quantities above the plan limit 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 chemotherapy*

OR

Drug and Biologic Coverage Criteria

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 **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 **for injection** are 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)

SANCUSO (granisetron) 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.

Drug and Biologic Coverage Criteria

CINVANTI 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 nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a 3-day regimen.

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

EMEND for **oral suspension** is indicated:

In combination with other antiemetic agents, in patients **6 months 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)

EMEND **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 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. Additional limitation of oral dosage forms: Chronic continuous administration of Emend is not recommended.

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

GRANISETRON is indicated for:

Prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin

ANZEMET 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 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.

COMPENDIAL APPROVED OFF-LABELED USES:

Granisetron for post-operative nausea/vomiting (PONV) prophylaxis

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	Dacarbazine
Carmustine	Mechlorethamine
Cyclophosphamide > 1,500 mg/m ²	Streptozocin

Moderate (30%-90%)

Alemtuzumab	Doxorubicin
Arsenic trioxide	Epirubicin
Azacitidine	Fam-trastuzumabderuxtecan-nxki
Bendamustine	Idarubicin
Busulfan	Ifosfamide
Carboplatin	Irinotecan
Clofarabine	Irinotecan liposomal injection
Cyclophosphamide, 1,500mg/m ²	Oxaliplatin
Cytarabine 1,000 mg/m ²	Romidepsin
Daunorubicin	Temozolomide
Daunorubicin and cytarabine liposome	Thiotepab
	Trabected

Low (10%-30%)

Aflibercept	Ixabepilone
Axicabtagene ciloleucel	Methotrexate
Belinostat	Mitomycin
Blinatumomab	Mitoxantrone
Bortezomib	Moxetumomab
Brentuximab	pasudotox
Cabazitaxel	Nab-paclitaxel
Carfilzomib	Necitumumab
Catumaxumab	Nelarabine
Cetuximab	Paclitaxel
Copanlisib	Panitumumab
Cytarabine # 1,000 mg/m ²	Pegylated
Decitabine	liposomal
Docetaxel	doxorubicin
Elotuzumab	Pemetrexed
Enfortumab vedotin-ejfv	Pertuzumab
Eribulin	Tagraxofusp-erzs
Etoposide	Temsirolimus
Fluorouracil	Tisagenlecleucel
Gemcitabine	Topotecan
Gemtuzumab ozogamicin	Trastuzumab-emtansine
Inotuzumab ozogamicin	Vinflunine

Drug and Biologic Coverage Criteria

Minimal (<10%)

Atezolizumab	Nivolumab
Avelumab	Obinutuzumab
Bevacizumab	Ofatumumab
Bleomycin	Pembrolizumab
Cemiplimab	Pixantrone
Chlorodeoxyadenosine	Polatuzumab vedotin
Cladribine	Pralatrexate
Daratumumab	Ramucirumab
Durvalumab	Rituximab
Emapalumab	Trastuzumab
Fludarabine	Vinblastine
Ipilimumab	Vincristine
	Vinorelbine

Emetic Risk of Single, Oral Antineoplastic Agents in Adults

Moderate or high ($\geq 30\%$)

Abemaciclib	Lenvatinib
Avapritinib	Lomustine
Bosutinib	Midostaurin
Cabozantinib	Niraparib
Ceritinib	Procarbazine
Crizotinib	Ribociclib
Cyclophosphamide	Rucaparib
Enasidenib	Selinexor
Fedratinib	TAS-102 (trifluridine-tipiracil)
Hexamethylmelamine	Temozolomide
Imatinib	Vinorelbine

Minimal or low (< 30%)

6-Thioguanine	Lapatinib
Acalabrutinib	Larotrectinib
Afatinib	Lenalidomide
Alectinib	Lorlatinib
Alpelisib	Melphalan
Axitinib	Methotrexate
Bexarotene	Neratinib
Brigatinib	Nilotinib
Capecitabine	Olaparib
Chlorambucil	Osimertinib
Cobimetinib	Palbociclib
Dabrafenib	Panobinostat
Dacomitinib	Pazopanib
Dasatinib	Pexidartinib
Duvelisib	Pomalidomide
Encorafenib	Ponatinib
Entrectinib	Regorafenib
Erdafitinib	Ruxolitinib
Erlotinib	Sonidegib
Estramustine	Sorafenib
Etoposide	Sunitinib
Everolimus	Talazoparib
Fludarabine	Tazemetostat
Gefitinib	Tegafur-Uracil
Gilteritinib	Thalidomide
Glasdegib	Topotecan

Drug and Biologic Coverage Criteria

Hydroxyurea
Ibrutinib
Idelalisib
Ivosidenib
Ixazomib

Trametinib
Vandetanib
Vemurafenib
Venetoclax
Vismodegib
Vorinostat
Zanubrutinib

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.

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

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
J1260	Injection, dolasetron mesylate, 10 mg
J3490	Unclassified drug (Aponvie)

AVAILABLE DOSAGE FORMS:

Akynzeo CAPS 300-0.5MG Akynzeo SOLN 235-0.25MG/20ML Akynzeo SOLR 235-0.25MG
 Aloxi SOLN 0.25MG/5ML
 Anzemet TABS 100MG Anzemet TABS 50MG
 Aprepitant CAPS 125MG Aprepitant CAPS 40MG Aprepitant CAPS 80 & 125MG Aprepitant CAPS 80MG Aprepitant MISC 80 & 125MG
 Cinvanti EMUL 130MG/18ML Emend CAPS 125MG
 Emend CAPS 40MG
 Emend CAPS 80MG
 Emend SOLR 150MG
 Emend SUSR

125MG/5ML
 Emend Tri-Pack CAPS 80 & 125MG
 Fosaprepitant Dimeglumine SOLR 150MG
 Granisetron HCl SOLN 1MG/ML
 Granisetron HCl SOLN 4MG/4ML
 Palonosetron HCl SOLN 0.25MG/2ML
 Palonosetron HCl SOLN 0.25MG/5ML
 Palonosetron HCl SOSY 0.25MG/5ML
 Sancuso PTCH 3.1MG/24HR
 Sustol PRSY 10MG/0.4ML
 Varubi (180 MG Dose) TBPk 2 x 90MG
 Aponvie EMUL 32MG/4.4ML

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Drug and Biologic Coverage Criteria

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: 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	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file