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Policy Number: C20780-A

Antiemetics

PRODUCTS AFFECTED

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

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

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 a 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

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

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

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
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.

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 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 **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

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
- Carmustine
- Cyclophosphamide > 1,500 mg/m2
- Dacarbazine
- Mechlorethamine
- Streptozocin

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
- Doxorubicin
- Epirubicin
- Fam-trastuzumabderuxtecan-nxki
- Idarubicin
- Ifosfamide
- Irinotecan
- Irinotecan liposomal injection
- Oxaliplatin
- Romidepsin
- Temozolomidea
- Thiotepab
- Trabected

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
- 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

Minimal (<10%)

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

Emetic Risk of Single, Oral Antineoplastic Agents in Adults

Moderate or high (≥ 30%)

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

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
- 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

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 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

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

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SUMMARY OF REVIEW/REVISIONS	DATE
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