

**Generic Name:** Netupitant/Palonosetron

**Therapeutic Class or Brand Name:** Akynzeo capsules

**Applicable Drugs (if Therapeutic Class):** N/A

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 11/2/2014

**Date Last Reviewed / Revised:** 1/13/2024

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

- I. Documented diagnosis of prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy.
- II. Documented use of moderately- or highly-emetogenic antineoplastic agents (refer to Appendix, Table 1).
- III. Documentation that Akynzeo is being used in combination with dexamethasone.
- IV. Documented treatment failure or contraindication to two trials of preferred 5-HT3 receptor antagonists (ie, granisetron and ondansetron) when taken in combination with aprepitant.
- V. Minimum age requirement: 18 years old.
- VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

## EXCLUSION CRITERIA

- Concomitant use of a strong CYP3A4 inducer such as rifampin.
- Severe hepatic impairment (Child-Pugh score greater than 9).
- Severe renal impairment (CrCl < 30 ml/min) or end-stage renal disease.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- One capsule per chemotherapy course.

## APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

**APPENDIX**

Table 1. Emetic Risk Classification for Parenteral Antineoplastic Agents<sup>a</sup>

<p><b>High</b></p>	<ul style="list-style-type: none"> <li>• AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide</li> <li>• carboplatin AUC <math>\geq 4</math></li> <li>• carmustine (BiCNU) <math>&gt; 250 \text{ mg/m}^2</math></li> <li>• cisplatin</li> <li>• cyclophosphamide <math>&gt; 1,500 \text{ mg/m}^2</math></li> <li>• dacarbazine</li> <li>• doxorubicin <math>\geq 60 \text{ mg/m}^2</math></li> <li>• epirubicin <math>&gt; 90 \text{ mg/m}^2</math></li> <li>• fam-trastuzumab deruxtecan-nxki</li> <li>• ifosfamide <math>\geq 2 \text{ g/m}^2/\text{dose}</math></li> <li>• mechlorethamine (Mustargen)</li> <li>• melphalan <math>\geq 140 \text{ mg/m}^2</math></li> <li>• Sacituzumab govitecan-hziy</li> <li>• streptozocin (Zanosar)</li> </ul>
<p><b>Moderate</b></p>	<ul style="list-style-type: none"> <li>• Aldesleukin <math>&gt; 12\text{--}15 \text{ million IU/m}^2</math></li> <li>• Amifostine <math>&gt; 300 \text{ mg/m}^2</math></li> <li>• Bendamustine</li> <li>• Busulfan</li> <li>• Carboplatin<sup>b</sup> AUC <math>&lt; 4</math></li> <li>• Carmustine<sup>b</sup> <math>\leq 250 \text{ mg/m}^2</math></li> <li>• Clofarabine</li> <li>• Cyclophosphamide<sup>b</sup> <math>\leq 1500 \text{ mg/m}^2</math></li> <li>• Cytarabine <math>&gt; 200 \text{ mg/m}^2</math></li> <li>• Dactinomycin<sup>b</sup></li> <li>• Daunorubicin<sup>b</sup></li> <li>• Dinutuximab</li> <li>• Doxorubicin<sup>b</sup> <math>&lt; 60 \text{ mg/m}^2</math></li> <li>• Dual-drug liposomal encapsulation of cytarabine and daunorubicin</li> <li>• Epirubicin<sup>b</sup> <math>\leq 90 \text{ mg/m}^2</math></li> <li>• Idarubicin<sup>b</sup></li> <li>• Ifosfamide<sup>b</sup> <math>&lt; 2 \text{ g/m}^2</math> per dose</li> <li>• Irinotecan<sup>b</sup></li> <li>• Irinotecan (liposomal)</li> <li>• Lurbinectedin</li> <li>• Melphalan <math>&lt; 140 \text{ mg/m}^2</math></li> <li>• Methotrexate<sup>b</sup> <math>\geq 250 \text{ mg/m}^2</math></li> <li>• Naxitamab-gqgk</li> <li>• Oxaliplatin<sup>b</sup></li> <li>• Romidepsin</li> <li>• Temozolomide</li> <li>• Trabectedin<sup>b</sup></li> </ul>

<p><b>Low</b></p>	<ul style="list-style-type: none"> <li>• Ado-trastuzumab emtansine</li> <li>• Aldesleukin ≤12 million IU/m<sup>2</sup></li> <li>• Amifostine ≤300 mg/m<sup>2</sup></li> <li>• Amivantamab-vmjw</li> <li>• Arsenic trioxide</li> <li>• Axicabtagene ciloleucel</li> <li>• Azacitidine</li> <li>• Belinostat</li> <li>• Brexucabtagene autoleucel</li> <li>• Brentuximab vedotin</li> <li>• Cabazitaxel</li> <li>• Carfilzomib</li> <li>• Ciltacabtagene autoleucel</li> <li>• Copanlisib</li> <li>• Cytarabine (low dose) 100 mg/m<sup>2</sup> - 200 mg/m<sup>2</sup></li> <li>• Docetaxel</li> <li>• Doxorubicin (liposomal)</li> <li>• Enfortumab vedotin-ejfv</li> <li>• Eribulin</li> <li>• Etoposide</li> <li>• 5-Fluorouracil (5-FU)</li> <li>• Floxuridine</li> <li>• Gemcitabine</li> <li>• Gemtuzumab ozogamicin</li> <li>• Idecabtagene vicleucel</li> <li>• Inotuzumab ozogamicin</li> <li>• Isatuximab-irfc</li> <li>• Ixabepilone</li> <li>• Lisocabtagene maraleucel</li> <li>• Loncastuximab tesirine-lpyl</li> <li>• Methotrexate &gt;50 mg/m<sup>2</sup> - &lt;250 mg/m<sup>2</sup></li> <li>• Mitomycin</li> <li>• Mitomycin pyelocalyceal solution</li> <li>• Mitoxantrone</li> <li>• Mogamulizumab-kpkc</li> <li>• Moxetumomab pasudotoxdfk</li> <li>• Necitumumab</li> <li>• Omacetaxine</li> <li>• Paclitaxel</li> <li>• Paclitaxel-albumin</li> <li>• Pemetrexed</li> <li>• Pentostatin</li> <li>• Polatuzumab vedotin-piig</li> <li>• Pralatrexate</li> <li>• Tafasitamab-cxix</li> <li>• Tagraxofusp-erzs</li> <li>• Talimogene laherparepvec</li> <li>• Tebentafusp-tebn</li> <li>• Thiotepa</li> <li>• Tisagenlecleucel</li> <li>• Tisotumab vedotin-tftv</li> <li>• Topotecan</li> <li>• Ziv-aflibercept</li> </ul>
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<b>Minimal</b>	<ul style="list-style-type: none"> <li>• Alemtuzumab</li> <li>• Asparaginase</li> <li>• Atezolizumab</li> <li>• Avelumab</li> <li>• Belantamab mafodotin-blmf</li> <li>• Bevacizumab</li> <li>• Bleomycin</li> <li>• Blinatumomab</li> <li>• Bortezomib</li> <li>• Cemiplimab-rwlc</li> <li>• Cetuximab</li> <li>• Cladribine</li> <li>• Cytarabine &lt;100 mg/m<sup>2</sup></li> <li>• Daratumumab</li> <li>• Daratumumab and hyaluronidase-fihj</li> <li>• Decitabine</li> <li>• Dexrazoxane</li> <li>• Dostarlimab-gxly</li> <li>• Durvalumab</li> <li>• Elotuzumab</li> <li>• Fludarabine</li> <li>• Ipilimumab</li> <li>• Luspatercept-aamt</li> <li>• Margetuximab-cmkb</li> <li>• Methotrexate ≤50 mg/m<sup>2</sup></li> <li>• Nelarabine</li> </ul>	<ul style="list-style-type: none"> <li>• Nivolumab</li> <li>• Nivolumab/relatlimabrbmbw</li> <li>• Obinutuzumab</li> <li>• Ofatumumab</li> <li>• Panitumumab</li> <li>• Pembrolizumab</li> <li>• Pertuzumab</li> <li>• Pertuzumab/trastuzumab and hyaluronidase-zzxf</li> <li>• Ramucirumab</li> <li>• Rituximab</li> <li>• Rituximab and hyaluronidase</li> <li>• Siltuximab</li> <li>• Sirolimus-albumin</li> <li>• Teclistamab-cqyv</li> <li>• Temsirolimus</li> <li>• Trastuzumab</li> <li>• Trastuzumab and hyaluronidaseoysk</li> <li>• Tremelimumab-actl</li> <li>• Valrubicin</li> <li>• Vinblastine</li> <li>• Vincristine</li> <li>• Vincristine (liposomal)</li> <li>• Vinorelbine</li> </ul>
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<sup>a</sup> List is not exhaustive. Medications not listed here will be evaluated with the most recent versions of ASCO and NCCN, as well as their prescribing information.

<sup>b</sup> May be highly emetogenic in certain patients.

**REFERENCES**

1. Akynzeo. Prescribing information. Helsinn Therapeutics Inc; 2023. Accessed January 13, 2024. <https://www.akynzeo.com/assets/pdf/Akynzeo-USPI.pdf>
2. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: ASCO Guideline Update [published correction appears in J Clin Oncol. 2020 Nov 10;38(32):3825] [published correction appears in J Clin Oncol. 2021 Jan 1;39(1):96]. *J Clin Oncol.* 2020;38(24):2782-2797. doi:10.1200/JCO.20.01296
3. NCCN Clinical Practice Guidelines in Oncology. Antiemesis. Version 1.2024. Updated December 13, 2023. [https://www.nccn.org/professionals/physician\\_gls/pdf/antiemesis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf). Accessed January 13, 2024.

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**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.