



## MEDICATION POLICY

**Generic Name:** Netupitant/Palonosetron

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

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

**Date of Origin:** 11/21/14

**Date Last Reviewed/Revised:** 9/29/16

**GPI Code:** 5030990229

### **Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):**

- I. Documented diagnosis of prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy.
- II. Must meet ONE of the following criteria A OR B:
  - A. Documented use of moderately- or highly-emetogenic antineoplastic agents (as defined in Appendix).
  - B. Documented trial and failure of, intolerance to, or contraindication to two preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron).
- III. Minimum age requirement: 18 years old.

### **Exclusion Criteria:**

- Concomitant use in members who are chronically using a strong CYP3A4 inducer such as rifampin.

### **Other Criteria:**

- N/A

### **Quantity/Days Supply Restrictions:**

- One capsule per prescription.

### **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.

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## MEDICATION POLICY

**Appendix:**
**Emetic Risk Classification for IV Antineoplastic Agents<sup>a</sup>**

<b>High</b>	AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin) carmustine (BiCNU) > 250 mg/m <sup>2</sup> cisplatin cyclophosphamide > 1,500 mg/m <sup>2</sup> dacarbazine doxorubicin ≥ 60 mg/m <sup>2</sup> epirubicin > 90 mg/m <sup>2</sup> ifosfamide ≥ 2 g/m <sup>2</sup> /dose mechlorethamine (Mustargen) streptozocin (Zanosar)	
<b>Moderate</b>	aldesleukin (Proleukin) > 12-15 million IU/m <sup>2</sup> amifostine > 300 mg/m <sup>2</sup> arsenic trioxide (Trisenox) azacitidine (Vidaza) bendamustine (Treanda) busulfan (Myleran) carboplatin <sup>b</sup> carmustine (BiCNU) ≤ 250 mg/m <sup>2</sup> clofarabine (Clolar) cyclophosphamide ≤ 1,500 mg/m <sup>2</sup> cytarabine > 200 mg/m <sup>2</sup> dactinomycin <sup>b</sup> daunorubicin <sup>b</sup>	dinutuximab (Unituxin) doxorubicin < 60 mg/m <sup>2</sup> epirubicin ≤ 90 mg/m <sup>2</sup> idarubicin ifosfamide < 2 g/m <sup>2</sup> /dose <sup>b</sup> interferon alfa ≥ 10 million IU/m <sup>2</sup> irinotecan <sup>b</sup> melphalan methotrexate ≥ 250 mg/m <sup>2</sup> <sup>b</sup> oxaliplatin temozolomide IV (Temodar) trabectedin (Yondelis)
<b>Low</b>	ado-trastuzumab emtansine (Kadcyla) amifostine ≤ 300 mg/m <sup>2</sup> aldesleukin (Proleukin) ≤ 12 million IU/m <sup>2</sup> belinostat (Beleodaq) blinatumomab (Blinicyto) brentuximab vedotin (Adcetris) cabazitaxel (Jevtana) carfilzomib (Kyprolis) cytarabine 100-200 mg/m <sup>2</sup> docetaxel doxorubicin liposomal eribulin (Halaven) etoposide 5-fluorouracil (5-FU) floxuridine gemcitabine interferon alfa >5 <10 million IU/m <sup>2</sup>	irinotecan liposomal (Onivyde) ixabepilone (Ixempra) methotrexate > 50 < 250 mg/m <sup>2</sup> mitomycin mitoxantrone necitumumab (Portrazza) omacetaxine (Synribo) paclitaxel paclitaxel-albumin bound (Abraxane) pemetrexed (Alimta) pentostatin pralatrexate (Folotyn) romidepsin (Istodax) talimogene laherparepvec (Imlygic) thiotepa topotecan ziv-aflibercept (Zaltrap)

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# MEDICATION POLICY

## Emetic Risk Classification for IV Antineoplastic Agents <sup>a</sup>

<b>Minimal</b>	alemtuzumab (Campath, Lemtrada) asparaginase bevacizumab (Avastin) bleomycin bortezomib (Velcade) cetuximab (Erbix) cladribine (2-chlorodeoxyadenosine) cytarabine < 100 mg/m <sup>2</sup> daratumumab (Darzalex) decitabine denileukin diftitox (Ontak) dexrazoxane elotuzumab (Empliciti) fludarabine interferon alpha ≤ 5 million IU/m <sup>2</sup> ipilimumab (Yervoy) methotrexate ≤ 50 mg/m <sup>2</sup> nelarabine (Arranon)	nivolumab (Opdivo) obinutuzumab (Gazyva) ofatumumab (Arzerra) panitumumab (Vectibix) pegaspargase (Oncaspar) peginterferon pembrolizumab (Keytruda) pertuzumab (Perjeta) ramucirumab (Cyramza) rituximab (Rituxan) siltuximab (Sylvant) temsirolimus (Torisel) trastuzumab (Herceptin) valrubicin (Valstar) vinblastine vincristine vincristine liposomal (Marqibo) vinorelbine
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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 designated at a higher emetic risk if at a higher dose or used in certain combinations (i.e. with cyclophosphamide).

### References:

1. [http://www.nccn.org/professionals/physician\\_gls/pdf/antiemesis.pdf](http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf).
2. <http://www.asco.org/quality-guidelines/antiemetics-asco-clinical-practice-guideline-update>.
3. [https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL\\_REVIEW\\_CRITERIA/ANTIEMETICS\\_EFF\\_111115.PDF](https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL_REVIEW_CRITERIA/ANTIEMETICS_EFF_111115.PDF).
4. <http://blue.regence.com/trgmedpol/drugs/dru378.pdf>.
5. <http://blue.regence.com/trgmedpol/drugs/dru315.pdf>.
6. [Medi-Span](#).
7. [https://www.akynzeo.com/assets/pdf/Prescribing\\_Information.pdf](https://www.akynzeo.com/assets/pdf/Prescribing_Information.pdf).

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<b>Historical Tracking Of Changes Made To Policy</b>													
9/29/2016	<p>1. <b>Added the following to the table under Appendix: Emetic Risk Classification for IV Antineoplastic Agents<sup>a</sup></b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width: 15%; padding: 2px;"><b>Moderate</b></td> <td style="padding: 2px;">dinutuximab (Unituxin)</td> <td style="padding: 2px;">trabectedin (Yondelis)</td> </tr> <tr> <td style="padding: 2px;"><b>Low</b></td> <td style="padding: 2px;">irinotecan liposomal (Onivyde) necitumumab (Portrazza)</td> <td style="padding: 2px;">talimogene laherparepvec (Imlygic)</td> </tr> <tr> <td style="padding: 2px;"><b>Minimal</b></td> <td style="padding: 2px;">daratumumab (Darzalex)</td> <td style="padding: 2px;">elotuzumab (Empliciti)</td> </tr> </table> <p>2. <b>Updated</b>  <a href="https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL_REVIEW_CRITERIA/MEDICAL_REVIEW%20CRITERIA_ALOXI-EMEND_EFF102214_V2.PDF">"https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL_REVIEW_CRITERIA/MEDICAL_REVIEW%20CRITERIA_ALOXI-EMEND_EFF102214_V2.PDF"</a> to  <a href="https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL_REVIEW_CRITERIA/ANTIEMETICS_EFF_111115.PDF">"https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL_REVIEW_CRITERIA/ANTIEMETICS_EFF_111115.PDF"</a> and  <a href="http://www.akynzeo.com/media/Prescribing_Information.pdf">"http://www.akynzeo.com/media/Prescribing_Information.pdf"</a> to  <a href="https://www.akynzeo.com/assets/pdf/Prescribing_Information.pdf">"https://www.akynzeo.com/assets/pdf/Prescribing_Information.pdf"</a> <b>under References.</b></p>	<b>Moderate</b>	dinutuximab (Unituxin)	trabectedin (Yondelis)	<b>Low</b>	irinotecan liposomal (Onivyde) necitumumab (Portrazza)	talimogene laherparepvec (Imlygic)	<b>Minimal</b>	daratumumab (Darzalex)	elotuzumab (Empliciti)			
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4/11/2015	<p>1. <b>Changed "II. Must meet ONE of the following criteria A OR B: A. Documented use of highly-emetogenic chemotherapy (as defined in Appendix); B. Documented trial and failure of, intolerance to, or contraindication to ALL preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron)" to "II. Must meet ONE of the following criteria A OR B: A. Documented use of moderately- or highly-emetogenic antineoplastic agents (as defined in Appendix); B. Documented trial and failure of, intolerance to, or contraindication to two preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron)" under Prior Authorization Criteria.</b></p> <p>2. <b>Changed table under Appendix from:</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: left; padding: 5px;"><b>Emetic Risk Classification for IV Chemotherapy<sup>a</sup></b></th> </tr> </thead> <tbody> <tr> <td style="width: 15%; padding: 5px;"><b>High</b></td> <td colspan="2" style="padding: 5px;">AC: cyclophosphamide + anthracycline (daunorubicin, doxorubicin, epirubicin, idarubicin) carmustine cisplatin cyclophosphamide &gt;1,500 mg/m<sup>2</sup> dacarbazine (DTIC) dactinomycin doxorubicin &gt; 60 mg/m<sup>2</sup> epirubicin &gt;90 mg/m<sup>2</sup> ifosfamide ≥ 2gm/m<sup>2</sup>/dose mechlorethamine</td> </tr> <tr> <td style="padding: 5px;"><b>Moderate</b></td> <td style="padding: 5px;">aldesleukin (Proleukin) &gt; 12-15 million IU/m<sup>2</sup> alemtuzumab (Campath) amifostine &gt;300 mg/m<sup>2</sup> arsenic trioxide azacitidine (Vidaza) bendamustine (Treanda) busulfan carboplatin<sup>b</sup> clofarabine (Clolar) cyclophosphamide (Cytosan) ≤ 1,500 mg/m<sup>2b</sup> cytarabine &gt; 200 mg/m<sup>2</sup></td> <td style="padding: 5px;">Daunorubicin<sup>b</sup> doxorubicin ≤60 mg/m<sup>2b</sup> epirubicin ≤ 90 mg/m<sup>2b</sup> idarubicin<sup>b</sup> ifosfamide &lt; 2gm/m<sup>2b</sup> interferon alfa ≥ 10 million IU/m<sup>2</sup> irinotecan melphalan methotrexate ≥250 mg/m<sup>2</sup> oxaliplatin (Eloxatin) temozolomide IV (Temodar)</td> </tr> <tr> <td style="padding: 5px;"><b>Low</b></td> <td style="padding: 5px;">amifostine ≤ 300 mg aldesleukin (Proleukin) ≤ 12 million IU/m<sup>2b</sup> bortezomib (Velcade) brentuximab (Adcetris)</td> <td style="padding: 5px;">methotrexate &gt; 51-249 mg/m<sup>2b</sup> mitomycin mitoxantrone paclitaxel</td> </tr> </tbody> </table>	<b>Emetic Risk Classification for IV Chemotherapy<sup>a</sup></b>			<b>High</b>	AC: cyclophosphamide + anthracycline (daunorubicin, doxorubicin, epirubicin, idarubicin) carmustine cisplatin cyclophosphamide >1,500 mg/m <sup>2</sup> dacarbazine (DTIC) dactinomycin doxorubicin > 60 mg/m <sup>2</sup> epirubicin >90 mg/m <sup>2</sup> ifosfamide ≥ 2gm/m <sup>2</sup> /dose mechlorethamine		<b>Moderate</b>	aldesleukin (Proleukin) > 12-15 million IU/m <sup>2</sup> alemtuzumab (Campath) amifostine >300 mg/m <sup>2</sup> arsenic trioxide azacitidine (Vidaza) bendamustine (Treanda) busulfan carboplatin <sup>b</sup> clofarabine (Clolar) cyclophosphamide (Cytosan) ≤ 1,500 mg/m <sup>2b</sup> cytarabine > 200 mg/m <sup>2</sup>	Daunorubicin <sup>b</sup> doxorubicin ≤60 mg/m <sup>2b</sup> epirubicin ≤ 90 mg/m <sup>2b</sup> idarubicin <sup>b</sup> ifosfamide < 2gm/m <sup>2b</sup> interferon alfa ≥ 10 million IU/m <sup>2</sup> irinotecan melphalan methotrexate ≥250 mg/m <sup>2</sup> oxaliplatin (Eloxatin) temozolomide IV (Temodar)	<b>Low</b>	amifostine ≤ 300 mg aldesleukin (Proleukin) ≤ 12 million IU/m <sup>2b</sup> bortezomib (Velcade) brentuximab (Adcetris)	methotrexate > 51-249 mg/m <sup>2b</sup> mitomycin mitoxantrone paclitaxel
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	cabazitaxel (Jevtana) cytarabine 100-200 mg/m <sup>2</sup> <sup>b</sup> docetaxel (Taxotere) doxorubicin liposomal (Doxil) eribulin (Halaven) etoposide (VP-16) 5-fluorouracil (5-FU) floxuridine gemcitabine (Gemzar) interferon alfa 5-10 million IU/m <sup>2</sup> <sup>b</sup> ixabepilone (Ixempra)	paclitaxel-albumin bound (Abraxane) panitumumab (Vectibix) pemetrexed (Alimta) pentostatin pralatrexate (Folotyn) romidepsin (Istodax) temsirolimus (Torisel) thiotepa topotecan trastuzumab (Herceptin)
	<b>Minimal</b>	asparaginase (Elspar) bevacizumab (Avastin) bleomycin cetuximab (Erbix) cladribine (2-chlorodeoxyadenosine) fludarabine (Fludara) rituximab (Rituxan) vinblastine vincristine vinorelbine
Adapted from NCCN and ASCO Guidelines. <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 designated at a higher emetic risk if at a higher dose or used in certain combinations (i.e. with cyclophosphamide).		
<b>to:</b> <b>Emetic Risk Classification for IV Antineoplastic Agents <sup>a</sup></b>		
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<i>Historical Tracking Of Changes Made To Policy</i>		
		<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <ul style="list-style-type: none"> <li>belinostat (Beleodaq)</li> <li>blinatumomab (Blincyto)</li> <li>brentuximab vedotin (Adcetris)</li> <li>cabazitaxel (Jevtana)</li> <li>carfilzomib (Kyprolis)</li> <li>cytarabine 100-200 mg/m<sup>2</sup></li> <li>docetaxel</li> <li>doxorubicin liposomal</li> <li>eribulin (Halaven)</li> <li>etoposide</li> <li>5-fluorouracil (5-FU)</li> <li>floxuridine</li> <li>gemcitabine</li> </ul> </div> <div style="width: 48%;"> <ul style="list-style-type: none"> <li>mitomycin</li> <li>mitoxantrone</li> <li>omacetaxine (Synribo)</li> <li>paclitaxel</li> <li>paclitaxel-albumin bound (Abraxane)</li> <li>pemetrexed (Alimta)</li> <li>pentostatin</li> <li>pralatrexate (Folotyn)</li> <li>romidepsin (Istodax)</li> <li>thiotepa</li> <li>topotecan</li> <li>ziv-aflibercept (Zaltrap)</li> </ul> </div> </div>
	<b>Minimal</b>	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <ul style="list-style-type: none"> <li>alemtuzumab (Campath, Lemtrada)</li> <li>asparaginase</li> <li>bevacizumab (Avastin)</li> <li>bleomycin</li> <li>bortezomib (Velcade)</li> <li>cetuximab (Erbix)</li> <li>cladribine (2-chlorodeoxyadenosine)</li> <li>cytarabine &lt; 100 mg/m<sup>2</sup></li> <li>decitabine</li> <li>denileukin diftitox (Ontak)</li> <li>dexrazoxane</li> <li>fludarabine</li> <li>interferon alpha ≤ 5 million IU/m<sup>2</sup></li> <li>ipilimumab (Yervoy)</li> <li>methotrexate ≤ 50 mg/m<sup>2</sup></li> <li>nelarabine (Arranon)</li> <li>nivolumab (Opdivo)</li> </ul> </div> <div style="width: 48%;"> <ul style="list-style-type: none"> <li>obinutuzumab (Gazyva)</li> <li>ofatumumab (Arzerra)</li> <li>panitumumab (Vectibix)</li> <li>pegaspargase (Oncaspar)</li> <li>peginterferon</li> <li>pembrolizumab (Keytruda)</li> <li>pertuzumab (Perjeta)</li> <li>ramucirumab (Cyramza)</li> <li>rituximab (Rituxan)</li> <li>siltuximab (Sylvant)</li> <li>temsirolimus (Torisel)</li> <li>trastuzumab (Herceptin)</li> <li>valrubicin (Valstar)</li> <li>vinblastine</li> <li>vincristine</li> <li>vincristine liposomal (Marqibo)</li> <li>vinorelbine</li> </ul> </div> </div>
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