

**Generic Name:** Palonosetron HCL

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

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

**GPI Code:** 5025007010

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 2/4/2019

### PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when ONE of criteria I or II is met)

- I. Documented diagnosis of prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy AND criteria A and B are met:
  - A. Must meet ONE of the following criteria 1 OR 2:
    1. Documented use of moderately- or highly-emetogenic chemotherapy (as defined in Appendix).
    2. Documented trial and failure of, intolerance to, or contraindication to two preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron).
  - B. Minimum age requirement: 1 month old.
- II. Documented diagnosis of prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery AND criteria A and B are met:
  - A. Documented trial and failure of, intolerance to, or contraindication to two preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron).
  - B. Minimum age requirement: 18 years old.

### EXCLUSION CRITERIA

- N/A

### OTHER CRITERIA

- N/A

### QUANTITY / DAYS SUPPLY RESTRICTIONS

- One dose per prescription.

### APPROVAL LENGTH

- **Authorization:**
  -

- Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy: 6 months.
- PONV: One dose.
- **Re-Authorization:**
  - Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy: An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective.
  - PONV: N/A

**APPENDIX**

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

<b>High</b>	AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide carboplatin AUC $\geq 4$ carmustine (BiCNU) $> 250 \text{ mg/m}^2$ cisplatin cyclophosphamide $> 1,500 \text{ mg/m}^2$ dacarbazine doxorubicin $\geq 60 \text{ mg/m}^2$ epirubicin $> 90 \text{ mg/m}^2$ ifosfamide $\geq 2 \text{ g/m}^2/\text{dose}$ mechlorethamine (Mustargen) streptozocin (Zanosar)	
<b>Moderate</b>	aldesleukin (Proleukin) $> 12\text{-}15$ million IU/m <sup>2</sup> amifostine $> 300 \text{ mg/m}^2$ arsenic trioxide (Trisenox) azacitidine (Vidaza) bendamustine (Treanda) busulfan (Myleran) carboplatin AUC $< 4$ <sup>b</sup> carmustine (BiCNU) $\leq 250 \text{ mg/m}^2$ clofarabine (Clolar) cyclophosphamide $\leq 1,500 \text{ mg/m}^2$ cytarabine $> 200 \text{ mg/m}^2$ dactinomycin <sup>b</sup> daunorubicin <sup>b</sup>	dinutuximab (Unituxin) doxorubicin <sup>b</sup> $< 60 \text{ mg/m}^2$ epirubicin <sup>b</sup> $\leq 90 \text{ mg/m}^2$ idarubicin ifosfamide <sup>b</sup> $< 2 \text{ g/m}^2/\text{dose}$ interferon alfa $\geq 10$ million IU/m <sup>2</sup> irinotecan <sup>b</sup> melphalan methotrexate <sup>b</sup> $\geq 250 \text{ mg/m}^2$ oxaliplatin <sup>b</sup> temozolomide (Temodar) trabectedin <sup>b</sup> (Yondelis)

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

<p><b>Low</b></p>	<p>ado-trastuzumab emtansine (Kadcyla)                      aldesleukin (Proleukin) ≤ 12 million IU/m<sup>2</sup>                      amifostine ≤ 300 mg/m<sup>2</sup>                      atezolizumab                      belinostat (Beleodaq)                      blinatumomab (Blincyto)                      brentuximab vedotin (Adcetris)                      cabazitaxel (Jevtana)                      carfilzomib (Kyprolis)                      cytarabine (low dose) 100-200 mg/m<sup>2</sup>                      docetaxel                      doxorubicin liposomal                      eribulin (Halaven)                      etoposide                      5-fluorouracil (5-FU)                      floxuridine                      gemcitabine                      interferon alfa &gt;5 &lt;10 million IU/m<sup>2</sup></p>	<p>irinotecan liposomal (Onivyde)                      ixabepilone (Ixempra)                      methotrexate &gt; 50 &lt; 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)</p>
<p><b>Minimal</b></p>	<p>alemtuzumab (Campath, Lemtrada)                      asparaginase                      bevacizumab (Avastin)                      bleomycin                      bortezomib (Velcade)                      cetuximab (Erbix)                      cladribine (2-chlorodeoxyadenosine)                      cytarabine &lt; 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)</p>	<p>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</p>

<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. [http://www.nccn.org/professionals/physician\\_gls/pdf/antiemesis.pdf](http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf) .

2. <https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aloxi.pdf> .
3. NPS.
4. Medi-Span®.
5. <http://www.aloxi.com/docs/pdf/PI.pdf> .

**HISTORICAL TRACKING OF CHANGES MADE TO POLICY**

Date	Notes/Changes						
2/4/2019	<ol style="list-style-type: none"> <li>1. <b>Deleted</b> obsolete URLs in References items #3 and #4:                             <ul style="list-style-type: none"> <li>• <a href="http://blue.regence.com/trgmedpol/drugs/dru315.pdf">http://blue.regence.com/trgmedpol/drugs/dru315.pdf</a>.</li> <li>• <a href="http://blue.regence.com/trgmedpol/drugs/dru378.pdf">http://blue.regence.com/trgmedpol/drugs/dru378.pdf</a>.</li> </ul> </li> <li>2. <b>Deleted</b> item I in Prior Authorization Criteria section: "Documented diagnosis of one of the following conditions A through B AND must meet must meet criteria listed under each applicable diagnosis:".</li> <li>3. <b>Changed</b> heading <b>under Prior Authorization Criteria</b> "may be considered medically necessary when criteria I is met" to "may be considered medically necessary when ONE of criteria I or II is met".</li> <li>4. <b>Changed</b> all items <b>under Prior Authorization Criteria</b> list levels to UP one level</li> </ol>						
12/8/2017	<ol style="list-style-type: none"> <li>1. <b>Changed</b> "Authorization: 6 months" to "Authorization: Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy: 6 months; PONV: One dose" <b>under Approval Length</b>.</li> <li>2. <b>Changed</b> "Re-Authorization: An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective" to "Re-Authorization: Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy: An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective; PONV: N/A" <b>under Approval Length</b>.</li> <li>3. <b>Changed</b> "High: AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin)" to High: AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide", "Moderate: carboplatin <sup>b</sup>" to "Moderate: carboplatin AUC &lt; 4 <sup>b</sup>", "Moderate: doxorubicin &lt; 60 mg/m<sup>2</sup>" to "Moderate: doxorubicin <sup>b</sup> &lt; 60 mg/m<sup>2</sup>", "Moderate: epirubicin ≤ 90 mg/m<sup>2</sup>" to "Moderate: epirubicin <sup>b</sup> ≤ 90 mg/m<sup>2</sup>", "Moderate: oxaliplatin" to "Moderate: oxaliplatin <sup>b</sup>", "Moderate: temozolomide IV" to "Moderate: temozolomide", "Moderate: trabectedin" to "Moderate: trabectedin <sup>b</sup>", "Low: cytarabine 100-200 mg/m<sup>2</sup>" to "Low: cytarabine (low dose) 100-200 mg/m<sup>2</sup>", and "<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)" to "<sup>b</sup> May be highly emetogenic in certain patients" <b>on table under Appendix</b>.</li> <li>4. <b>Added</b> "High: carboplatin AUC ≥ 4" and "Low: atezolizumab" <b>on table under Appendix</b>.</li> </ol>						
9/29/2016	<ol style="list-style-type: none"> <li>1. <b>Added the following to the table under Appendix:</b>  <table border="1" data-bbox="410 1858 1377 1896"> <thead> <tr> <th colspan="3" data-bbox="410 1837 1068 1864"><b>Emetic Risk Classification for IV Antineoplastic Agents <sup>a</sup></b></th> </tr> </thead> <tbody> <tr> <td data-bbox="410 1864 586 1896"><b>Moderate</b></td> <td data-bbox="586 1864 971 1896">dinutuximab (Unituxin)</td> <td data-bbox="971 1864 1377 1896">trabectedin (Yondelis)</td> </tr> </tbody> </table> </li> </ol>	<b>Emetic Risk Classification for IV Antineoplastic Agents <sup>a</sup></b>			<b>Moderate</b>	dinutuximab (Unituxin)	trabectedin (Yondelis)
<b>Emetic Risk Classification for IV Antineoplastic Agents <sup>a</sup></b>							
<b>Moderate</b>	dinutuximab (Unituxin)	trabectedin (Yondelis)					

	<table border="1"> <tr> <td data-bbox="410 262 589 321"><b>Low</b></td> <td data-bbox="589 262 971 321">irinotecan liposomal (Onivyde) necitumumab (Portrazza)</td> <td data-bbox="971 262 1377 321">talimogene laherparepvec (Imlygic)</td> </tr> <tr> <td data-bbox="410 321 589 359"><b>Minimal</b></td> <td data-bbox="589 321 971 359">daratumumab (Darzalex)</td> <td data-bbox="971 321 1377 359">elotuzumab (Empliciti)</td> </tr> </table>	<b>Low</b>	irinotecan liposomal (Onivyde) necitumumab (Portrazza)	talimogene laherparepvec (Imlygic)	<b>Minimal</b>	daratumumab (Darzalex)	elotuzumab (Empliciti)
<b>Low</b>	irinotecan liposomal (Onivyde) necitumumab (Portrazza)	talimogene laherparepvec (Imlygic)					
<b>Minimal</b>	daratumumab (Darzalex)	elotuzumab (Empliciti)					
4/11/2015	<ol style="list-style-type: none"> <li><b>Changed</b> "I. Documented diagnosis of prevention and/or treatment of chemotherapy-induced nausea/vomiting associated with moderately- or highly-emetogenic chemotherapy (as defined in Appendix); II. Must have failed or have a contraindication to all preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron); III. Minimum age requirement: 18 years old" to "I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy AND criteria 1 and 2 are met: 1. Must meet ONE of the following criteria a OR b: a. Documented use of moderately- or highly-emetogenic chemotherapy (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); 2. Minimum age requirement: 1 month old; B. Prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery AND criteria 1 and 2 are met: 1. Documented trial and failure of, intolerance to, or contraindication to two preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron); 2. Minimum age requirement: 18 years old" <b>under Prior Authorization Criteria.</b></li> <li><b>Changed</b> "No other 5-HT3 receptor antagonists allowed as rescue drugs" to "N/A" <b>under Exclusion Criteria.</b></li> <li><b>Changed</b> "One dose (one 0.25mg/5mL vial) per chemotherapy cycle, not to exceed four doses per month (up to four of the 0.25mg/5mL vials)" to "One dose per prescription" <b>under Quantity/Days Supply Restrictions.</b></li> <li><b>Changed table under Appendix from:</b> <table border="1" data-bbox="386 1167 1511 1528"> <tr> <th colspan="2" data-bbox="391 1171 1507 1205"><b>Emetic Risk Classification for IV Chemotherapy<sup>a</sup></b></th> </tr> <tr> <td data-bbox="391 1205 545 1524"><b>High</b></td> <td data-bbox="545 1205 1507 1524">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> </table> </li> </ol>	<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		
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<p><b>Moderate</b></p>	<p>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 (Cytoxan) ≤ 1,500 mg/m<sup>2b</sup>                      cytarabine &gt; 200 mg/m<sup>2</sup></p>	<p>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)</p>
<p><b>Low</b></p>	<p>amifostine ≤ 300 mg                      aldesleukin (Proleukin) ≤12 million IU/m<sup>2b</sup>                      bortezomib (Velcade)                      brentuximab (Adcetris)                      cabazitaxel (Jevtana)                      cytarabine 100-200 mg/m<sup>2b</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>2b</sup>                      ixabepilone (Ixempra)</p>	<p>methotrexate &gt;51-249 mg/m<sup>2b</sup>                      mitomycin                      mitoxantrone                      paclitaxel                      paclitaxel-albumin bound (Abraxane)                      panitumumab (Vectibix)                      pemetrexed (Alimta)                      pentostatin                      pralatrexate (Folotyng)                      romidepsin (Istodax)                      temsirolimus (Torisel)                      thiotepa                      topotecan                      trastuzumab (Herceptin)</p>
<p><b>Minimal</b></p>	<p>asparaginase (Elspar)                      bevacizumab (Avastin)                      bleomycin                      cetuximab (Erbix)                      cladribine (2-chlorodeoxyadenosine)</p>	<p>fludarabine (Fludara)                      rituximab (Rituxan)                      vinblastine                      vincristine                      vinorelbine</p>
<p><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 (e.g. with cyclophosphamide).                      to:</p>		
<p><b>Emetic Risk Classification for IV Antineoplastic Agents <sup>a</sup></b></p>		
<p><b>High</b></p>	<p>AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin)                      carmustine (BiCNU) &gt; 250 mg/m<sup>2</sup>                      cisplatin                      cyclophosphamide &gt; 1,500 mg/m<sup>2</sup>                      dacarbazine                      doxorubicin ≥ 60 mg/m<sup>2</sup>                      epirubicin &gt; 90 mg/m<sup>2</sup>                      ifosfamide ≥ 2 g/m<sup>2</sup>/dose                      mechlorethamine (Mustargen)                      streptozocin (Zanosar)</p>	

<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> 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)
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<b>Minimal</b>	alemtuzumab (Campath, Lemtrada) asparaginase bevacizumab (Avastin) bleomycin bortezomib (Velcade) cetuximab (Erbix) cladribine (2-chlorodeoxyadenosine) cytarabine < 100 mg/m <sup>2</sup> decitabine denileukin diffitox (Ontak) dexrazoxane 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

<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.

	<p><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).</p> <p>5. <b>Added</b> "<a href="http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf">http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf</a>" and "<a href="http://blue.regence.com/trgmedpol/drugs/dru378.pdf">http://blue.regence.com/trgmedpol/drugs/dru378.pdf</a>" <b>under References.</b></p> <p>6. <b>Updated</b> "<a href="http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Aloxi.pdf">http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Aloxi.pdf</a>" to "" <b>under References.</b></p>
<p>11/13/213</p>	<ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Changed GPI Code from</b> "50250070102010, 50250070102020" <b>to</b> "5025007010".</li> <li>3. <b>Changed</b> "Documented diagnosis of prevention of acute or delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy" <b>to</b> "Documented diagnosis of prevention and/or treatment of chemotherapy-induced nausea/vomiting associated with moderately- or highly-emetogenic chemotherapy (as defined in Appendix)" <b>under Prior Authorization Criteria.</b></li> <li>4. <b>Added</b> "Minimum age requirement: 18 years old" <b>requirement under Prior Authorization Criteria.</b></li> <li>5. <b>Changed</b> "5ml per prescription" <b>to</b> "One dose (one 0.25mg/5mL vial) per chemotherapy cycle, not to exceed four doses per month (up to four of the 0.25mg/5mL vials)" <b>under Quantity/Days Supply Restrictions.</b></li> <li>6. <b>Changed</b> "Repeat course of chemotherapy following initial 6 months requires new authorization" <b>to</b> "An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective" <b>under Re-Authorization.</b></li> <li>7. <b>Added</b> "Emetic Risk Classification for IV Chemotherapy" <b>table in Appendix.</b></li> <li>8. <b>Updated references</b> to include specific Utah Medicaid and Regence policies referred to and website address for Aloxi package insert.</li> </ol>
<p>Click or tap to enter a date.</p>	

**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.