MEDICATION POLICY

Generic Name: Palonosetron HCL

Therapeutic Class or Brand Name: Aloxi®

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

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/8/17

GPI Code: 5025007010

Prior Authorization Criteria (may be considered medically necessary when criterion I is met):

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.

Exclusion Criteria:

- N/A

Other Criteria:

- N/A

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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 [a]

High	AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide carboplatin AUC $\geq$ 4 carmustine (BiCNU) > 250 mg/m^2 cisplatin cyclophosphamide > 1,500 mg/m^2 dacarbazine doxorubicin $\geq$ 60 mg/m^2 epirubicin > 90 mg/m^2 ifosfamide $\geq$ 2 g/m^2/dose mechlorethamine (Mustargen) streptozocin (Zanosar)

Emetic Risk Classification for IV Antineoplastic Agents [a]

Moderate	aldesleukin (Proleukin) > 12-15 million IU/m^2 amifostine > 300 mg/m^2 arsenic trioxide (Trisenox) azacitidine (Vidaza) bendamustine (Treanda) busulfan (Myleran) carboplatin AUC < 4 [b] carmustine (BiCNU) ≤ 250 mg/m^2 clofarabine (Clolar) cyclophosphamide ≤ 1,500 mg/m^2 cytarabine > 200 mg/m^2 dactinomycin [b] daunorubicin [b]	dinutuximab (Unituxin) doxorubicin [b] < 60 mg/m^2 epirubicin [b] ≤ 90 mg/m^2 idarubicin ifosfamide [b] < 2 g/m^2/dose interferon alfa ≥ 10 million IU/m^2 irinotecan [b] melphalan methotrexate [b] ≥ 250 mg/m^2 oxaliplatin [b] temozolomide (Temodar) trabectedin [b] (Yondelis)
Low	ado-trastuzumab emtansine (Kadcyla) aldesleukin (Proleukin) ≤ 12 million IU/m^2 amifostine ≤ 300 mg/m^2 atezolizumab belinostat (Beleodaq) blinatumomab (Blincyto) brentuximab vedotin (Adcetris) cabazitaxel (Jevtana) carfilzomib (Kyprolis) cytarabine (low dose) 100-200 mg/m^2 docetaxel doxorubicin liposomal eribulin (Halaven) etoposide 5-fluorouracil (5-FU) floxuridine gemcitabine interferon alfa >5 <10 million IU/m^2	irinotecan liposomal (Onivyde) ixabepilone (Ixempra) methotrexate > 50 < 250 mg/m^2 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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Emetic Risk Classification for IV Antineoplastic Agents [a]

Minimal	alemtuzumab (Campath, Lemtrada)	nivolumab (Opdivo)
	asparaginase	obinutuzumab (Gazyva)
	bevacizumab (Avastin)	ofatumumab (Arzerra)
	bleomycin	panitumumab (Vectibix)
	bortezomib (Velcade)	pegaspargase (Oncaspar)
	cetuximab (Erbitux)	peginterferon
	cladribine (2-chlorodeoxyadenosine)	pembrolizumab (Keytruda)
	cytarabine < 100 mg/m^2	pertuzumab (Perjeta)
	daratumumab (Darzalex)	ramucirumab (Cyramza)
	decitabine	rituximab (Rituxan)
	denileukin diftitox (Ontak)	siltuximab (Sylvant)
	dexrazoxane	temsirolimus (Torisel)
	elotuzumab (Empliciti)	trastuzumab (Herceptin)
	fludarabine	valrubicin (Valstar)
	interferon alpha ≤ 5 million IU/m^2	vinblastine
	ipilimumab (Yervoy)	vincristine
	methotrexate ≤ 50 mg/m^2	vincristine liposomal (Marqibo)
	nelarabine (Arranon)	vinorelbine

[a] 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.
[b] May be highly emetogenic in certain patients.

References:

1. http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf.
2. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aloxi.pdf.
3. http://blue.regence.com/trgmedpol/drugs/dru315.pdf.
4. http://blue.regence.com/trgmedpol/drugs/dru378.pdf.
5. NPS.
6. Medi-Span.
7. http://www.aloxi.com/docs/pdf/PI.pdf.

MEDICATION POLICY

<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td>12/8/2017</td><td>1. Changed “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” under Approval Length.
2. Changed “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” under Approval Length.
3. Changed “High: AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin)” to High: AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide”, “Moderate: carboplatin [b]” to “Moderate: carboplatin AUC < 4 [b]”, “Moderate: doxorubicin < 60 mg/m^2” to “Moderate: doxorubicin [b] < 60 mg/m^2”, “Moderate: epirubicin ≤ 90 mg/m^2” to “Moderate: epirubicin [b] ≤ 90 mg/m^2”, “Moderate: oxaliplatin” to “Moderate: oxaliplatin [b]”, “Moderate: temozolomide IV” to “Moderate: temozolomide”, “Moderate: trabectedin” to “Moderate: trabectedin [b]”, “Low: cytarabine 100-200 mg/m^2” to “Low: cytarabine (low dose) 100-200 mg/m^2”, and “[b] May be designated at a higher emetic risk if at a higher dose or used in certain combinations (i.e. with cyclophosphamide)” to “[b] May be highly emetogenic in certain patients” on table under Appendix.
4. Added “High: carboplatin AUC ≥ 4” and “Low: atezolizumab” on table under Appendix.</td></tr>
<tr><td>9/29/2016</td><td>1. Added the following to the table under Appendix:
Emetic Risk Classification for IV Antineoplastic Agents [a]
<table>
<tr><td>Moderate</td><td>dinutuximab (Unituxin)</td><td>trabectedin (Yondelis)</td></tr>
<tr><td>Low</td><td>irinotecan liposomal (Onivyde)
necitumumab (Portrazza)</td><td>talimogene laherparepvec (Imlygic)</td></tr>
<tr><td>Minimal</td><td>daratumumab (Darzalex)</td><td>elotuzumab (Empliciti)</td></tr>
</table></td></tr>
<tr><td>4/11/2015</td><td>1. Changed “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” under Prior Authorization Criteria.
2. Changed “No other 5-HT3 receptor antagonists allowed as rescue drugs” to “N/A” under Exclusion Criteria.
3. Changed “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” under Quantity/Days Supply Restrictions.
4. Changed table under Appendix from:
Emetic Risk Classification for IV Chemotherapy[a]</td></tr>
</table>

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 judgment in providing the most appropriate care for their patients.

Historical Tracking Of Changes Made To Policy

High	AC: cyclophosphamide + anthracycline (daunorubicin, doxorubicin, epirubicin, idarubicin) carmustine cisplatin cyclophosphamide >1,500 mg/m^2 dacarbazine (DTIC) dactinomycin doxorubicin >60 mg/m^2 epirubicin >90 mg/m^2 ifosfamide ≥ 2gm/m^2/dose mechlorethamine	
Moderate	aldesleukin (Proleukin) > 12-15 million IU/m^2 alemtuzumab (Campath) amifostine >300 mg/m^2 arsenic trioxide azacitidine (Vidaza) bendamustine (Treanda) busulfan carboplatin[b] clofarabine (Clolar) cyclophosphamide (Cytoxan) ≤ 1,500 mg/m^{2b} cytarabine > 200 mg/m^2	daunorubicin[b] doxorubicin ≤60 mg/m^{2b} epirubicin ≤ 90 mg/ m^{2b} idarubicin[b] ifosfamide < 2gm/m^{2b} interferon alfa ≥ 10 million IU/m^2 irinotecan melphalan methotrexate ≥250 mg/ m^2 oxaliplatin (Eloxatin) temozolomide IV (Temodar)
Low	amifostine ≤ 300 mg aldesleukin (Proleukin) ≤12 million IU/m^{2b} bortezomib (Velcade) brentuximab (Adcetris) cabazitaxel (Jevtana) cytarabine 100-200 mg/m^{2b} docetaxel (Taxotere) doxorubicin liposomal (Doxil) eribulin (Halaven) etoposide (VP-16) 5-fluorouracil (5-FU) floxuridine gemcitabine (Gemzar) interferon alfa 5-10 million IU/m^{2b} ixabepilone (Ixempra)	methotrexate >51-249 mg/m^{2b} mitomycin mitoxantrone paclitaxel paclitaxel-albumin bound (Abraxane) panitumumab (Vectibix) pemetrexed (Alimta) pentostatin pralatrexate (Folotyn) romidepsin (Istodax) temsirolimus (Torisel) thiotepa topotecan trastuzumab (Herceptin)
Minimal	asparaginase (Elspar) bevacizumab (Avastin) bleomycin cetuximab (Erbitux) cladribine (2-chlorodeoxyadenosine)	fludarabine (Fludara) rituximab (Rituxan) vinblastine vincristine vinorelbine

[a]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.

[b]May be designated at a higher emetic risk if at a higher dose or used in certain combinations (e.g. with cyclophosphamide).

to:

Emetic Risk Classification for IV Antineoplastic Agents [a]

High	AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin)

Historical Tracking Of Changes Made To Policy				
			carmustine (BiCNU) > 250 mg/m^2 cisplatin cyclophosphamide > 1,500 mg/m^2 dacarbazine doxorubicin ≥ 60 mg/m^2 epirubicin > 90 mg/m^2 ifosfamide ≥ 2 g/m^2/dose mechlorethamine (Mustargen) streptozocin (Zanosar)	
		Moderate	aldesleukin (Proleukin) > 12-15 million IU/m^2 amifostine > 300 mg/m^2 arsenic trioxide (Trisenox) azacitidine (Vidaza) bendamustine (Treanda) busulfan (Myleran) carboplatin [b] carmustine (BiCNU) ≤ 250 mg/m^2 clofarabine (Clolar) cyclophosphamide ≤ 1,500 mg/m^2 cytarabine > 200 mg/m^2 dactinomycin [b]	daunorubicin [b] doxorubicin < 60 mg/m^2 epirubicin ≤ 90 mg/m^2 idarubicin ifosfamide < 2 g/m^2/dose [b] interferon alfa ≥ 10 million IU/m^2 irinotecan [b] melphalan methotrexate ≥ 250 mg/m^2 [b] oxaliplatin temozolomide IV (Temodar)
		Low	ado-trastuzumab emtansine (Kadcyla) amifostine ≤ 300 mg/m^2 aldesleukin (Proleukin) ≤ 12 million IU/m^2 belinostat (Beleodaq) blinatumomab (Blincyto) brentuximab vedotin (Adcetris) cabazitaxel (Jevtana) carfilzomib (Kyprolis) cytarabine 100-200 mg/m^2 docetaxel doxorubicin liposomal eribulin (Halaven) etoposide 5-fluorouracil (5-FU) floxuridine gemcitabine	interferon alfa >5 <10 million IU/m^2 ixabepilone (Ixempra) methotrexate > 50 < 250 mg/m^2 mitomycin mitoxantrone omacetaxine (Synribo) paclitaxel paclitaxel-albumin bound (Abraxane) pemetrexed (Alimta) pentostatin pralatrexate (Folotyn) romidepsin (Istodax) thiotepa topotecan ziv-aflibercept (Zaltrap)
		Minimal	alemtuzumab (Campath, Lemtrada) asparaginase bevacizumab (Avastin) bleomycin bortezomib (Velcade) cetuximab (Erbitux) cladribine (2-chlorodeoxyadenosine) cytarabine < 100 mg/m^2 decitabine denileukin diftitox (Ontak) dexrazoxane	obinutuzumab (Gazyva) ofatumumab (Arzerra) panitumumab (Vectibix) pegaspargase (Oncaspar) peginterferon pembrolizumab (Keytruda) pertuzumab (Perjeta) ramucirumab (Cyramza) rituximab (Rituxan) siltuximab (Sylvant) temsirolimus (Torisel)

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Historical Tracking Of Changes Made To Policy	
	fludarabine / trastuzumab (Herceptin) interferon alpha ≤ 5 million IU/m^2 / valrubicin (Valstar) ipilimumab (Yervoy) / vinblastine methotrexate ≤ 50 mg/m^2 / vincristine nelarabine (Arranon) / vincristine liposomal (Marqibo) nivolumab (Opdivo) / vinorelbine [a] 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. [b] May be designated at a higher emetic risk if at a higher dose or used in certain combinations (i.e. with cyclophosphamide). 5. **Added** "http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf" **and** "http://blue.regence.com/trgmedpol/drugs/dru378.pdf"**under References**. 6. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Aloxi.pdf" **to** "" **under References**.
11/13/2013	1. **Adapted policy to new format.** 2. **Changed GPI Code from** "50250070102010, 50250070102020" **to** "5025007010". 3. **Changed** "Documented diagnosis of prevention of acute or delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy" **to** "Documented diagnosis of prevention and/or treatment of chemotherapy-induced nausea/vomiting associated with moderately- or highly-emetogenic chemotherapy (as defined in Appendix)" **under Prior Authorization Criteria**. 4. **Added** "Minimum age requirement: 18 years old" **requirement under Prior Authorization Criteria**. 5. **Changed** "5ml per prescription" **to** "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)" **under Quantity/Days Supply Restrictions**. 6. **Changed** "Repeat course of chemotherapy following initial 6 months requires new authorization" **to** "An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective" **under Re-Authorization**. 7. Added "Emetic Risk Classification for IV Chemotherapy" **table in Appendix**. 8. **Updated references** to include specific Utah Medicaid and Regence policies referred to and website address for Aloxi package insert.