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:** 9/29/16

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:** 6 months.
- **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.

Appendix:

Emetic Risk Classification for IV Antineoplastic Agents [a]

High	AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin) 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]	dinutuximab (Unituxin) 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) trabectedin (Yondelis)

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Emetic Risk Classification for IV Antineoplastic Agents [a]

Low	ado-trastuzumab emtansine (Kadcyla)	irinotecan liposomal (Onivyde)
	amifostine ≤ 300 mg/m^2	ixabepilone (Ixempra)
	aldesleukin (Proleukin) ≤ 12 million IU/m^2	methotrexate > 50 < 250 mg/m^2
	belinostat (Beleodaq)	mitomycin
	blinatumomab (Blincyto)	mitoxantrone
	brentuximab vedotin (Adcetris)	necitumumab (Portrazza)
	cabazitaxel (Jevtana)	omacetaxine (Synribo)
	carfilzomib (Kyprolis)	paclitaxel
	cytarabine 100-200 mg/m^2	paclitaxel-albumin bound (Abraxane)
	docetaxel	pemetrexed (Alimta)
	doxorubicin liposomal	pentostatin
	eribulin (Halaven)	pralatrexate (Folotyn)
	etoposide	romidepsin (Istodax)
	5-fluorouracil (5-FU)	talimogene laherparepvec (Imlygic)
	floxuridine	thiotepa
	gemcitabine	topotecan
	interferon alfa >5 <10 million IU/m^2	ziv-aflibercept (Zaltrap)
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 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.
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.

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</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:
<table>
<tr><td colspan="3">Emetic Risk Classification for IV Chemotherapy[a]</td></tr>
<tr><td>High</td><td colspan="2">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</td></tr>
<tr><td>Moderate</td><td>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</td><td>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)</td></tr>
</table></td></tr>
</table>

Historical Tracking Of Changes Made To Policy

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) 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)

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Historical Tracking Of Changes Made To Policy	
	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; fludarabine; interferon alpha ≤ 5 million IU/m^2; ipilimumab (Yervoy); methotrexate ≤ 50 mg/m^2; 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 [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**.

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Historical Tracking Of Changes Made To Policy	
	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.