MEDICATION POLICY

Generic Name: Aprepitant, Fosaprepitant

Therapeutic Class or Brand Name: Emend®

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

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/29/16

GPI Code: 5028002000, 5028003510

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 chemotherapy induced nausea and vomiting (CINV) associated with moderately- or highly-emetogenic antineoplastic agents (as defined in Appendix) and criterion 1 is met:

1. Minimum age requirement: 6 months old.

B. Prevention of postoperative nausea and vomiting (PONV) 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:

- Emend® should not be used concurrently with pimozide, terfenadine, astemizole, or cisapride, since inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Capsules:
  - CINV: Up to three capsules (i.e. one 125mg capsule plus two 80mg capsules) per prescription.
  - PONV: One 40mg capsule per prescription.

- Injection: 1 vial per prescription.
- Suspension: Up to three suspension pouches 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)

MEDICATION POLICY

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/Emend.pdf.

3. http://blue.regence.com/trgmedpol/drugs/dru315.pdf.
4. http://blue.regence.com/trgmedpol/drugs/dru378.pdf.
5. NPS.
6. http://www.merck.com/product/usa/pi_circulars/e/emend/emend_pi.pdf?WT.mc_id=N02N3.
7. http://www.merck.com/product/usa/pi_circulars/e/emend_iv/emend_iv_pi.pdf.

MEDICATION POLICY

<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td>9/29/2016</td><td>1. Changed “I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Prevention of chemotherapy induced nausea and vomiting (CINV) associated with moderately- or highly-emetogenic antineoplastic agents (as defined in Appendix); B. Prevention of postoperative nausea and vomiting (PONV) AND criterion 1 is met: 1. Documented trial and failure of, intolerance to, or contraindication to two preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron); II. 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 chemotherapy induced nausea and vomiting (CINV) associated with moderately- or highly-emetogenic antineoplastic agents (as defined in Appendix) and criterion 1 is met: 1. Minimum age requirement: 6 months old; B. Prevention of postoperative nausea and vomiting (PONV) 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. Added “Suspension: Up to three suspension pouches per prescription” under Quantity/Days Supply Restrictions.
3. 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 of nausea and vomiting associated with moderately- or highly-emetogenic chemotherapy (as defined in Appendix)” to “I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Prevention of chemotherapy induced nausea and vomiting (CINV) associated with moderately- or highly-emetogenic antineoplastic agents (as defined in Appendix); B. Prevention of postoperative nausea and vomiting (PONV) AND criterion 1 is met: 1. 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.
2. Changed “Capsules: 3 capsules (one 125mg capsule plus two 80mg capsules) per prescription” to “Capsules: CINV: Up to three capsules (i.e. one 125mg capsule plus two 80mg capsules) per prescription; PONV: One 40mg capsule per prescription” under Quantity/Days Supply Restrictions.
3. 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</td><td>daunorubicin[b]
doxorubicin ≤60 mg/m^2[b]
epirubicin ≤ 90 mg/ m^2[b]</td></tr>
</table></td></tr>
</table>

Historical Tracking Of Changes Made To Policy

	arsenic trioxide azacitidine (Vidaza) bendamustine (Treanda) busulfan carboplatin[b] clofarabine (Clolar) cyclophosphamide (Cytoxan) ≤ 1,500 mg/m^2[b] cytarabine > 200 mg/m^2	idarubicin[b] ifosfamide < 2gm/m^2[b] 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^2[b] bortezomib (Velcade) brentuximab (Adcetris) cabazitaxel (Jevtana) cytarabine 100-200 mg/m^2[b] docetaxel (Taxotere) doxorubicin liposomal (Doxil) eribulin (Halaven) etoposide (VP-16) 5-fluorouracil (5-FU) floxuridine gemcitabine (Gemzar) interferon alfa 5-10 million IU/m^2[b] ixabepilone (Ixempra)	methotrexate >51-249 mg/m^2[b] 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)	daunorubicin [b] doxorubicin < 60 mg/m^2 epirubicin ≤ 90 mg/m^2 idarubicin

Historical Tracking Of Changes Made To Policy

	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]	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 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).

4. **Added** "http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf" **and** "http://blue.regence.com/trgmedpol/drugs/dru378.pdf" **under References**.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
	5. **Removed** "http://blue.regence.com/trgmedpol/drugs/dru091.pdf" **from References** (link no longer valid). 6. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Emend.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Emend.pdf" **under References**.
12/2/2013	1. **Adapted policy to new format.** 2. **Added** "fosaprepitant" **to Generic Name**. 3. **Added GPI code** for fosaprepitant. 4. **Changed** "Patients receiving cancer chemotherapy regimens that are classified as high emetic risk may receive Emend® as first-line treatment; Patients on other cancer chemotherapy regimens must have failed or have a contraindication to all preferred 5-HT3 receptor antagonists (i.e. granisetron and ondansetron)" **to** "Documented diagnosis of prevention of nausea and vomiting associated with moderately- or highly-emetogenic chemotherapy (as defined in Appendix)" **under Prior Authorization Criteria**. 5. **Added** "Minimum age requirement: 18 years old" **to Prior Authorization Criteria**. 6. **Added** "Emend® should not be used concurrently with pimozide, terfenadine, astemizole, or cisapride, since inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions" **to Exclusion Criteria**. 7. **Changed Quantity/Days Supply Restrictions from** "Capsules: 5 capsules per prescription" **to** "Capsules: 3 capsules (one 125mg capsule plus two 80mg capsules) per prescription". 8. **Changed Authorization under Approval Length from** "6 months, 3 doses per chemotherapy session" **to** "6 months". 9. **Changed Re-Authorization under Approval Length from** "Updated letter of medical necessity" **to** "An updated letter of medical necessity or progress notes showing that current prior authorization criteria are met and that the medication is effective". 10. **Updated references** to include Regence Aloxi policy (used for table in Appendix) and Emend package inserts.