Reference number(s)
16-J

Post Limit Prior Authorization
Antiemetic 5-HT3
Antiemetic Agents – 5-HT3 Antagonists

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Anzemet	dolasetron mesylate	all
granisetron hydrochloride (brand unavailable)	granisetron hydrochloride	all
ondansetron (brand unavailable)	ondansetron	oral disintegrating tablet
ondansetron hydrochloride (brand unavailable)	ondansetron hydrochloride	tablet, oral solution, injection
Palonosetron Hydrochloride	palonosetron hydrochloride	all
palonosetron hydrochloride (brand unavailable)	palonosetron hydrochloride	all
Posfrea	palonosetron hydrochloride	all
Sancuso	granisetron	transdermal system
Sustol	granisetron extended-release	injection

Indications

FDA-approved Indications

Anzemet Tablets

Anzemet tablets are indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older.

Granisetron Hydrochloride

Granisetron Hydrochloride Tablets

Granisetron hydrochloride tablets USP are indicated for the prevention of:

- Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

Granisetron Hydrochloride Injection:

Granisetron hydrochloride injection, USP is a serotonin-3 (5-HT3) receptor antagonist indicated for:

- The prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- The prevention and treatment of postoperative nausea and vomiting in adults. As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided during the postoperative period, granisetron hydrochloride injection USP is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Ondansetron Injection

Prevention of Nausea and Vomiting Associated with Initial and Repeat Courses of Emetogenic Cancer Chemotherapy

Ondansetron injection is indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Ondansetron injection is approved for patients aged 6 months and older.

Prevention of Postoperative Nausea and/or Vomiting

Ondansetron injection is indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients in whom nausea and/or vomiting must be avoided postoperatively, ondansetron injection is recommended even when the incidence of postoperative nausea and/or vomiting is low. For patients who do not receive prophylactic ondansetron

injection and experience nausea and/or vomiting postoperatively, ondansetron injection may be given to prevent further episodes. Ondansetron injection is approved for patients aged 1 month and older.

Ondansetron Tablets, ODT, and Oral Solution

Ondansetron tablets, orally disintegrating tablets, and oral solution are indicated for the prevention of nausea and vomiting associated with:

- highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m^2.
- initial and repeat courses of moderately emetogenic cancer chemotherapy.
- radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.

Ondansetron tablets, orally disintegrating tablets, and oral solution are also indicated for the prevention of postoperative nausea and/or vomiting.

Palonosetron Hydrochloride Injection 2 mL single-dose vial

Palonosetron hydrochloride (HCl) injection is indicated for:

- Moderately emetogenic cancer chemotherapy - prevention of acute and delayed nausea and vomiting associated with initial and repeat courses.
- Highly emetogenic cancer chemotherapy - prevention of acute nausea and vomiting associated with initial and repeat courses.

Palonosetron Hydrochloride Injection 5 mL single-dose vial

Palonosetron hydrochloride injection is indicated in adults for prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- acute nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC).
- postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and vomiting must be avoided during the postoperative period, palonosetron hydrochloride is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Palonosetron hydrochloride injection is indicated in pediatric patients 1 months to less than 17 years of age for prevention of:

- acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy.

Posfrea

Posfrea is indicated in adults for prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- acute nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC).
- postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and vomiting must be avoided during the postoperative period, Posfrea is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Posfrea is indicated in pediatric patients 1 months to less than 17 years of age for prevention of:

- acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy.

Sancuso Transdermal System

Sancuso is indicated for the prevention of nausea and vomiting in adults receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration.

Sustol Extended-Release Injection

Sustol is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Compendial Uses:

- Treatment and/or prophylaxis of radiation-induced nausea and vomiting[14]

Compendial Uses Ondansetron Only

- Hyperemesis Gravidarum[14,15]

Coverage Criteria

Hyperemesis Gravidarum

Authorization may be granted for the diagnosis of Hyperemesis Gravidarum when ALL of the following criteria are met:

- The patient is pregnant.
- The patient has a documented risk for hospitalization.
- The request is for ondansetron.
- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following medications: dimenhydrinate (Dramamine),

diphenhydramine (Benadryl), doxylamine/pyridoxine delayed-release (Diclegis), doxylamine/pyridoxine extended-release (Bonjesta), metoclopramide (Reglan), promethazine (Phenergan), trimethobenzamide (Tigan), vitamin B6, vitamin B6 in combination with doxylamine.

Radiation Therapy or Moderate to Highly Emetogenic Chemotherapy

Authorization may be granted when the patient is receiving radiation therapy or moderate to highly emetogenic chemotherapy.

Duration of Approval (DOA):

- 16-J: DOA: 6 months

References

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3. Granisetron Hydrochloride Injection [package insert]. E. Windsor, NJ: AuroMedics Pharma LLC; December 2021.
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6. Ondansetron Orally Disintegrating Tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; November 2021.
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8. Palonosetron Injection [package insert]. Princeton, NJ: Dr Reddy's; August 2020.
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10. Posfrea Injection [package insert]. New Jersey: Avyxa Pharma, LLC; July 2024.
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12. Sustol Injection [package insert]. San Diego, CA: Heron Therapeutics, Inc.; May 2023.
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Document History

Written by: UM Development (LS)

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Revised: 12/1998, 11/1999; (JG) 08/2002; (MG) 07/2003, 10/2004, 04/2005; (AK) 07/2006; (CT) 04/2007, 04/2008, 10/2008(2) (Sancuso added; (SE) 03/2009, 01/2010 (removed Aloxi caps 03/2009(2)); (KD) 03/2010, 07/2010 (Zuplenz added); (SE) 01/2011 (FDA Warning/ CI 03-2010 (2)); (CY) 04/2011(updated algorithms), (CY) 02/2012, 05/2012 (Removed Q10 days/weeks per month and included in Q5&6 for CAS Web compatibility), 07/2012 (removed single use ondansetron 32mg); (PL) 01/2013; (MS) 09/2013, (PL) 01/2014; (CF) 01/2015, 03/2015, (LN) 04/2015 (added denial reasons); (CF) 01/2016, 09/2016 (added palonosetron injection), 12/2016 (added Diclegis and Bonjesta to t/f question); (KM) 01/2017 (added Sustol injection), (ME) 01/2018 (no clinical changes), 01/2019, 01/2020 (no clinical changes), 08/2020 (updated denial reasons), 12/2020 (updated denial reasons), 01/2021 (no clinical changes), (MRS) 01/2022 (no clinical changes), (TM/KJ) 12/2022 (removed brand Aloxi); (KEJ) 12/2023 (removed brand Zofran), 09/2024 (added Posfrea); (NSS) 12/2024 (removed Zuplenz)

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CRITERIA FOR APPROVAL

1	Is the patient receiving radiation therapy or moderate to highly emetogenic chemotherapy? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the patient pregnant with the diagnosis of Hyperemesis Gravidarum AND has a documented risk for hospitalization?	Yes	No

[If Yes, then go to 3. If No, then no further questions.]

3	Is this request for ondansetron? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to TWO of the following: A) dimenhydrinate (Dramamine), B) diphenhydramine (Benadryl), C) doxylamine/pyridoxine delayed-release (Diclegis), D) doxylamine/pyridoxine extended-release (Bonjesta), E) metoclopramide (Reglan), F) promethazine (Phenergan), G) trimethobenzamide (Tigan), H) vitamin B6, I) vitamin B6 in combination with doxylamine? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Approve, 6 Months	Go to 2	
2.	Go to 3	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage]. Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to the following per 28 days: A) 12 tablets of Anzemet 50 mg, B) 12 tablets of granisetron HCl, C) 2 mL of granisetron HCl injection, D) 20 mL of ondansetron injection, E) 2 tablets of ondansetron 24 mg, F) 18 tablets of ondansetron 4 mg or 8 mg tablets/ODT, G) 9 tablets of ondansetron 16 mg ODT, H) 200 mL of ondansetron oral solution, I) 4 mL of Palonosetron HCl injection (0.25 mg/2 mL), J) 10 mL of palonosetron HCl injection (0.25 mg/5 mL), K) 10 mL of Posfrea (palonosetron HCl injection (0.25 mg/5 mL)), L) 12 mL of Posfrea (palonosetron HCl injection (0.075 mg/1.5 mL)), M) 2 patches of Sancuso, N) 0.8 mL of Sustol. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]

3.	Go to 4	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage]. Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to the following per 28 days: A) 12 tablets of Anzemet 50 mg, B) 12 tablets of granisetron HCl, C) 2 mL of granisetron HCl injection, D) 20 mL of ondansetron injection, E) 2 tablets of ondansetron 24 mg, F) 18 tablets of ondansetron 4 mg or 8 mg tablets/ODT, G) 9 tablets of ondansetron 16 mg ODT, H) 200 mL of ondansetron oral solution, I) 4 mL of Palonosetron HCl injection (0.25 mg/2 mL), J) 10 mL of palonosetron HCl injection (0.25 mg/5 mL), K) 10 mL of Posfrea (palonosetron HCl injection (0.25 mg/5 mL)), L) 12 mL of Posfrea (palonosetron HCl injection (0.075 mg/1.5 mL)), M) 2 patches of Sancuso, N) 0.8 mL of Sustol. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]
4.	Approve, 6 Months	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage]. Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to the following per 28 days: A) 12 tablets of Anzemet 50 mg, B) 12 tablets of granisetron HCl, C) 2 mL of granisetron HCl injection, D) 20 mL of ondansetron injection, E) 2 tablets of ondansetron 24 mg, F) 18 tablets of ondansetron 4 mg or 8 mg tablets/ODT, G) 9 tablets of ondansetron 16 mg ODT, H) 200 mL of ondansetron oral solution, I) 4 mL of Palonosetron HCl injection (0.25 mg/2 mL), J) 10 mL of palonosetron HCl injection (0.25 mg/5 mL), K) 10 mL of Posfrea (palonosetron HCl injection (0.25 mg/5 mL)), L) 12 mL of Posfrea (palonosetron HCl injection (0.075 mg/1.5 mL)), M) 2 patches of Sancuso, N) 0.8 mL of Sustol. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug

			policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]