

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS ANTIEMETIC AGENTS – 5HT3 ANTAGONISTS

BRAND NAME
(generic)

ALOXI INJECTION
(palonosetron hydrochloride)

ANZEMET
(dolasetron mesylate)

(granisetron hydrochloride) (ALL PRODUCTS)
(palonosetron hydrochloride injection)

SANCUSO
(granisetron transdermal system)

SUSTOL
(granisetron extended-release injection)

ZOFRAN (ALL DOSAGE FORMS)
(ondansetron, ondansetron hydrochloride)

ZUPLENZ
(ondansetron oral soluble film)

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Aloxi Injection

Chemotherapy-Induced Nausea and Vomiting in Adults

Aloxi 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

Chemotherapy-Induced Nausea and Vomiting in Pediatric Patients Aged 1 Month to Less than 17 Years

Aloxi is indicated for prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy.

Postoperative Nausea and Vomiting in Adults

Aloxi is indicated for prevention of 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, Aloxi is recommended even where the incidence of postoperative nausea and/or vomiting is low.

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

Granisetron Tablets

Granisetron Hydrochloride Tablets 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 Injection:

Granisetron Hydrochloride Injection 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.

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 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 is approved for patients aged 1 month and older.

Palonosetron Hydrochloride Injection

Chemotherapy-Induced Nausea and Vomiting in Adults

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

Sancuso Transdermal System

Sancuso (granisetron transdermal system) is indicated for the prevention of nausea and vomiting in patients 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.

Zofran Tablets, Zofran ODT, and Zofran Oral Solution

Zofran is indicated for the prevention of nausea and vomiting associated with:

- highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m².
- 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.

Zofran is also indicated for the prevention of postoperative nausea and/or vomiting.

Zuplenz

Prevention of Nausea and Vomiting Associated with Highly Emetogenic Cancer Chemotherapy

Zuplenz (ondansetron) oral soluble film is indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin \geq 50 mg/m²

Prevention of Nausea and Vomiting Associated with Moderately Emetogenic Cancer Chemotherapy

Zuplenz is indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy

Prevention of Nausea and Vomiting Associated with Radiotherapy

Zuplenz is indicated for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen

Prevention of Postoperative Nausea and/or Vomiting

Zuplenz 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 where nausea and/or vomiting must be avoided postoperatively, Zuplenz is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Compendial Uses:

- Treatment and/or prophylaxis of radiation-induced nausea and vomiting.¹²

Compendial Use Ondansetron Only:

- Hyperemesis Gravidarum^{12,13}

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is receiving radiation therapy or moderate to highly emetogenic chemotherapy.

OR

- The request is for Zofran, Zuplenz or ondansetron **AND**
- The patient is pregnant with the diagnosis of Hyperemesis Gravidarum and a documented risk for hospitalization **AND**
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to two of the following medications: A) vitamin B6, B) vitamin B6 in combination with doxylamine, C) doxylamine/pyridoxine extended-release (Bonjesta), D) doxylamine/pyridoxine delayed-release (Diclegis), E) promethazine (Phenergan), F) trimethobenzamide (Tigan), G) metoclopramide (Reglan), H) diphenhydramine (Benadryl), I) dimenhydrinate (Dramamine)

REFERENCES

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