

QUANTITY LIMIT CRITERIA

DRUG CLASS	ANTIEMETICS
BRAND NAME (generic)	ZOFRAN (all dosage forms) (ondansetron and ondansetron hydrochloride)
	ZUPLENZ (ondansetron oral soluble film)
Status: CVS Caremark Criteria	
Type: Quantity Limit	

POLICY

FDA-APPROVED INDICATIONS

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.

Zofran Injection

Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy

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

Prevention of postoperative nausea and/or vomiting

Zofran 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, Zofran injection is recommended even when the incidence of postoperative nausea and/or vomiting is low. For patients who do not receive prophylactic Zofran injection and experience nausea and/or vomiting postoperatively, Zofran injection may be given to prevent further episodes. Zofran is approved for patients aged 1 month and older.

Zuplenz

Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy.

Zofran-Zuplenz Limit Policy 01-2018

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Zuplenz (ondansetron) oral soluble film is indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin $\geq 50 \text{ mg/m}^2$

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.

REFERENCES

1. Zofran Tablets, Zofran ODT, and Zofran Oral Solution [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2016.
2. Zofran Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2017.
3. Zuplenz [package insert]. Raleigh, NC: Midatech Pharma US Inc.; July 2017.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January 2018.
5. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 2018.
6. Hesketh PJ, Bohlke K, Lyman GH, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Onc* 34 (4); 2016; 381-386.
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. V.2.2016. Available at: www.nccn.org. Accessed January 2018.

LIMIT CRITERIA

Drug	4 Weeks Limit and 12 Weeks Limit*
Ondansetron 24 mg tablets	2 tablets / 21 days
Zofran 4 mg and 8 mg tablets/ODT tablets	18 tablets / 21 days
Zofran oral solution	200 mL / 21 days
Zofran injection	20 mL / 21 days (available in boxes of 5 vials of 2 mL each)
Zuplenz oral soluble film	18 films / 21 days

*** This drug is indicated for short-term acute use; therefore, the mail limit will be the same as the retail limit. The duration of 21 days is used for a 28-day fill period.**