

# QUANTITY LIMIT CRITERIA

<b>DRUG CLASS</b>	<b>ANTIEMETICS</b>
<b>BRAND NAME (generic)</b>	<b>ZOFRAN (ALL DOSAGE FORMS) (ondansetron and ondansetron hydrochloride)</b>
	<b>ZUPLENZ (ondansetron oral soluble film)</b>
<b>Status: CVS Caremark Criteria</b>	
<b>Type: Quantity Limit</b>	

## POLICY

### FDA-APPROVED INDICATIONS

#### **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.

#### **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/m<sup>2</sup>
- 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/m<sup>2</sup>

##### 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. Ondansetron Injection [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC.; December 2019.
2. Zofran Tablets, Zofran ODT, and Zofran Oral Solution [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; October 2017.
3. Zuplenz [package insert]. Raleigh, NC: Fortovia Therapeutics Inc.; June 2019.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed January 2021.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed January 2021.
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. V.1.2021. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/antiemesis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf). Accessed January 2021.

### LIMIT CRITERIA

**Limits do not accumulate together, patient is allowed the maximum limit for each drug and strength**

<u>Drug</u>	<u>4 Week Limit*</u>	<u>12 Week Limit*</u>
Ondansetron 24 mg tablets	2 tablets / 21 days	Does Not Apply*
Ondansetron (Zofran) 4 mg and 8 mg tablets/ODT tablets	18 tablets / 21 days	Does Not Apply*
Ondansetron (Zofran) oral solution	200 mL / 21 days	Does Not Apply*
Ondansetron injection	20 mL / 21 days (available in boxes of 5 vials of 2 mL each)	Does Not Apply*
Zuplenz oral soluble film	18 films / 21 days	Does Not Apply*

\* The duration of 21 days is used for a 28-day fill period to allow time for refill processing.

**\* These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.**