

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Ondansetron Agents Quantity Limit

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Strength	Quantity Limit
Zofran (ondansetron)	4mg tablets 8mg tablets 24mg tablets 4mg/ 5mL oral solution	48 tabs/ 30 days 24 tabs/ 30 days 8 tabs/ 30 days 240 mL/ 30 days
Zofran ODT (ondansetron)	4mg ODT tablets 8mg ODT tablets	48 tabs/ 30 days 24 tabs/ 30days
Zuplenz (ondansetron)	4mg soluble films 8mg soluble films	48 films/30 days 24 films/30 days

### APPROVAL CRITERIA

- I. For prevention of chemotherapy or radiotherapy induced nausea and vomiting, due to daily chemotherapy or radiotherapy; **OR**
- II. Treatment of nausea and vomiting related to palliative care after trial of and insufficient response or intolerance or contraindication to dopamine receptor antagonist therapy (NCCN Guidelines Version 1.2018, Palliative Care);

May approve the following quantity override amounts:

Medication	Override Limit
Zofran (ondansetron) 4 mg tablets	180 tablets per 30 days
Zofran (ondansetron) 8 mg tablets	90 tablets per 30 days
Zofran (ondansetron) 24 mg tablets	30 tablets per 30 days
Zofran (ondansetron) 4 mg/5 mL oral solution	900 mL per 30 days
Zofran ODT (ondansetron orally disintegrating) 4 mg tablets	180 tablets per 30 days
Zofran ODT (ondansetron orally disintegrating) 8 mg tablets	90 tablets per 30 days
Zuplenz (ondansetron) 4 mg soluble film	180 films per 30 days
Zuplenz (ondansetron) 8 mg soluble film	90 films per 30 days

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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**OR**

III. For treatment of nausea and vomiting in pregnancy (including hyperemesis gravidarum), may approve up to the following quantities AFTER a trial of pyridoxine (vitamin B6) either alone or in combination with doxylamine PLUS one of the following medications (ACOG 2018):

- A. H1 antagonist (such as, dimenhydrinate, diphenhydramine); **OR**
- B. Phenothiazine (such as, promethazine, prochlorperazine);

May approve the following quantity override amounts:

Medication	Override Limit
Zofran (ondansetron) 4 mg tablets	90 tablets per 30 days
Zofran (ondansetron) 8 mg tablets	90 tablets per 30 days
Zofran (ondansetron) 4 mg/5 mL oral solution	450 mL per 30 days
Zofran ODT (ondansetron orally disintegrating) 4 mg tablets	90 tablets per 30 days
Zofran ODT (ondansetron orally disintegrating) 8 mg tablets	90 tablets per 30 days
Zuplenz (ondansetron) 4 mg soluble film	90 films per 30 days
Zuplenz (ondansetron) 8 mg soluble film	90 films per 30 days

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 27, 2018.
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5. American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 189: Nausea and Vomiting of Pregnancy. *Obstetrics and gynecology*. 2018; 131(1): e15-e30. Available from [https://journals.lww.com/greenjournal/Fulltext/2018/01000/ACOG\\_Practice\\_Bulletin\\_No\\_189\\_Nausea\\_And.39.aspx](https://journals.lww.com/greenjournal/Fulltext/2018/01000/ACOG_Practice_Bulletin_No_189_Nausea_And.39.aspx). Accessed September 27, 2018.
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9. Pasternak B, Svanström H, Hviid A. Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes. *N Engl J Med*. 2013; 368:814-23. DOI: **10.1056/NEJMoa1211035**.

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