

Ondansetron Agents Quantity Limit

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

Medications	Strength	Quantity Limit
ondansetron tablets/oral solution	4mg tablets 8mg tablets 24mg tablets 4mg/ 5mL oral solution	48 tablets/ 30 days 24 tablets/ 30 days 8 tablets/ 30 days 240 mL/ 30 days
ondansetron ODT	4mg ODT tablets 8mg ODT tablets 16mg ODT tablets	48 tablets/ 30 days 24 tablets/ 30days 4 tablets/ 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 1.2024, Palliative Care);

May approve the following quantity override amounts:

Medication	Override Limit
ondansetron 4 mg tablets	180 tablets per 30 days
ondansetron 8 mg tablets	90 tablets per 30 days
ondansetron 24 mg tablets	30 tablets per 30 days
ondansetron 4 mg/5 mL oral solution	900 mL per 30 days
ondansetron orally disintegrating 4 mg tablets	180 tablets per 30 days
ondansetron orally disintegrating 8 mg tablets	90 tablets per 30 days

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
ondansetron 4 mg/5 mL oral solution	450 mL per 30 days
ondansetron orally disintegrating 4 mg tablets	90 tablets per 30 days
ondansetron orally disintegrating 8 mg tablets	90 tablets per 30 days

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
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. Accessed October 4, 2022.
6. Hesketh PJ, Kris MG, Basch E, et al. [Antiemetics: ASCO Guideline Update](#). Journal of Clinical Oncology 2020 38:24, 2782-2797. Available at <https://ascopubs.org/doi/pdf/10.1200/JCO.20.01296>. Accessed October 4, 2022.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 9, 2024.
 - a. Antiemesis. V2.2024. Revised September 27, 2024.
 - b. Palliative Care. V1.2024. Revised February 16, 2024.
8. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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