

# **Ondansetron**

**Adjudication Guideline (External instruction)** 

**Rule Category:** Pharmaceutical

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**Approved by:** Daman

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Related Adjudication Guidelines: N/A



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### 1. Abstract

#### 1.1 For Members

Ondansetron is indicated for the management of nausea and vomiting associated with chemotherapy, radiotherapy, and surgery. It is particularly useful for patients who are at risk of severe nausea or vomiting following these treatments. This medication must be taken under medical supervision.

### 1.2 For Medical Professionals

Ondansetron is primarily indicated for the management of nausea and vomiting associated with cancer chemotherapy, radiation therapy, and surgical procedures.

### 2. Scope

The scope of this adjudication rule highlights the medical indications and coverage requirements of Ondansetron drug for all health insurance plans administered by Daman as per policy terms and conditions.

Ondansetron is a selective 5-HT3 receptor antagonist used primarily to manage nausea and vomiting caused by cancer chemotherapy, radiation therapy, and surgery. It can be administered orally, rectally, intramuscularly or intravenously.

#### **Mechanism of Action:**

Receptor Blocking:

Ondansetron selectively inhibits the 5-HT3 receptors, found in the gastrointestinal tract and the brain's chemoreceptor trigger zone (CTZ).

Peripheral Effects:

By blocking 5-HT3 receptors in the gut, ondansetron reduces serotonin-induced nausea and vomiting.

Central Effects:

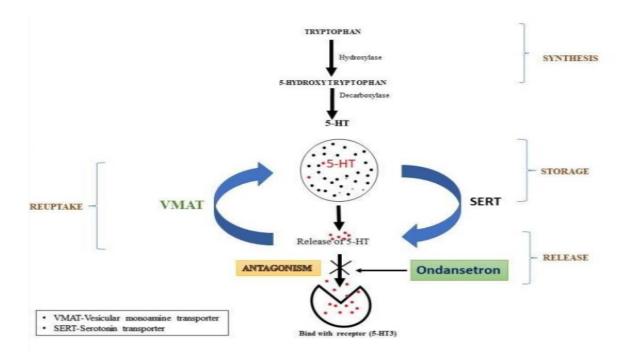
In the CTZ, the ondansetron prevents nausea and vomiting triggered by stimuli like chemotherapy and radiation.

Tissue Selectivity:

With a high affinity for 5-HT3 receptors, Ondansetron effectively manages nausea and vomiting while minimizing side effects compared to other antiemetics.

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# 3. Adjudication policy

### 3.1 Eligibility / Coverage Criteria

Ondansetron is intended for use under the guidance of a healthcare provider if medically justified .

### 3.2 Therapeutic indications

- 1. Management of Chemotherapy-Induced Nausea and Vomiting (CINV)
- 2. Management of Radiotherapy-Induced Nausea and Vomiting (RINV)
- 3. Management of Postoperative Nausea and Vomiting (PONV)
- 4. Management of nausea and vomiting associated with gastroenteritis and colitis

  The Oral form of Ondansetron is **Not** considered as a first-line treatment
- 5. Cyclic Vomiting Syndrome in Children:
  - An idiopathic disorder characterized by recurrent, stereotypical bouts of vomiting with intervening periods of normal or baseline health.
- 6. Nausea and Vomiting in Pregnancy (NVP)

Ondansetron is recommended as second-line treatment, preferably after the first trimester, if other treatments fail.

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• Pregnant Patients before 10 Weeks of Gestation:

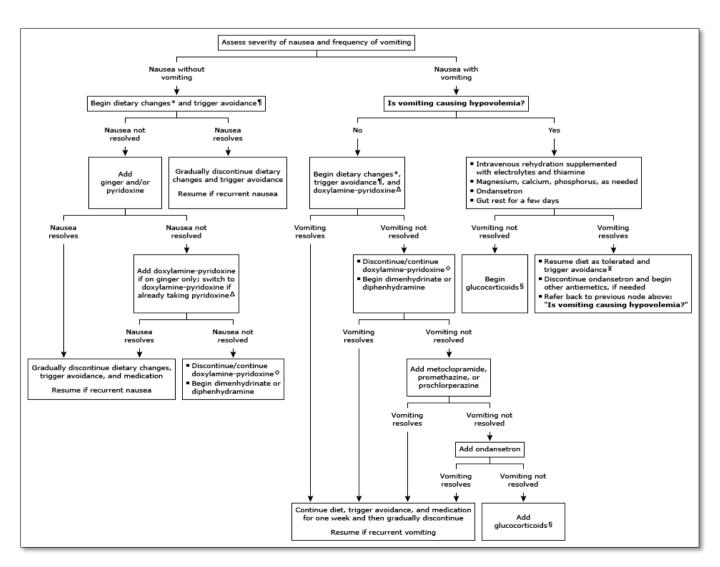
Use of ondansetron before 10 weeks of gestation is suspected to cause orofacial malformations. It should only be considered when first-line treatments have failed or if the patient develops complications such as dehydration or poor oral intake that could endanger maternal or fetal health — on a case-by-case basis through appeals.

- Pregnant Patients Between 10 to 20 Weeks of Gestation:
  - Presenting with nausea and vomiting accompanied by symptoms of hypovolemia, following the clinical step therapy algorithm (see *Image 1*).
- Pregnant Patients Beyond 20 Weeks of Gestation:

Coverage for ondansetron will be considered on a case-by-case basis, as most patients experience resolution of nausea and vomiting after 20 weeks. Therapy beyond this period is typically reserved for rare cases requiring medical justification.

#### Pregnant patients between 10 to 20 weeks of gestation treatment algorithm:

#### \*Image 1



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### 3.3 Requirements for Coverage

• Kindly code the ICD-10 and the CPT codes to the highest level of specificity

#### Red flags:

- Ondansetron is not covered for conditions outside its approved indications, including diagnoses such as "vomiting, unspecified" or "vomiting without accompanying nausea" when reported as standalone diagnosis
- Coverage does not extend to patients without a documented risk of moderate to severe nausea and vomiting.
- Use of ondansetron before 10 weeks of gestation is associated with a small increased risk of oral clefts. It should only be considered when first-line treatments have failed or if complications like dehydration or poor oral intake threaten maternal or fetal health.
- Ondansetron may cause cardiac adverse events, including QT prolongation, arrhythmias, and ischemia. It should be used with extreme caution in patients with existing cardiac conditions or a history of arrhythmia, and avoided if the patient is on other medications known to prolong the QT interval.
- No studies have evaluated the use of orally administered ondansetron for prevention or treatment of postoperative nausea and vomiting (PONV) in children aged  $\geq 1$  month. In such cases, IV administration is recommended.
- Patients presenting to the emergency department with severe, self-limiting nausea and vomiting due to causes such as viral gastroenteritis, acute mountain sickness, palliative care, or other medical conditions should be treated in emergency settings.
- The Oral form of Ondansetron is considered a second-line treatment for nausea and vomiting associated with gastroenteritis and colitis, except in emergency settings or IP

### 3.4 Non-coverage

Not covered for visitor plans

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### 4. Denial Codes

• Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

Code	Code Description
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
CODE-010	Activity/diagnosis inconsistent with clinician specialty
NCOV-001	Service(s) is (are) not covered
AUTH-001	Prior-Approval is required and was not obtained
MNEC-005	Service/supply may be appropriate, but too frequent
MNEC-006	Alternative drug should be used -Step therapy

## 5. Appendices

#### 5.1 References

ZOFRAN (ondansetron hydrochloride) Label

Ondansetron 4 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc)

National Comprehensive Cancer Network (NCCN) Guidelines for Antiemesis, Version 1.2021.

https://doi.org/10.1213/01.ane.0000295230.55439.f4

Radiotherapy-induced nausea and vomiting: Prophylaxis and treatment - UpToDate

https://www.nice.org.uk/advice/esuom34/ifp/chapter/about-ondansetronRCOG

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https://pmc.ncbi.nlm.nih.gov/articles/PMC9545331/

https://www.somanz.org/content/uploads/2020/07/NVP-GUIDELINE-1.2.20-1.pdf

 $\underline{\text{https://www.nnuh.nhs.uk/publication/download/hyperemesis-gravidarum-g6-v5/}}$ 

 $\underline{\text{https://obgyn.onlinelibrary.wiley.com/doi/epdf/} 10.1111/1471-0528.17739}$ 

 $\underline{\text{https://www.uptodate.com/contents/nausea-and-vomiting-of-pregnancy-treatment-and-}}$ 

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Ondansetron 4 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) | 10159

### 5.2 Revision History

Date	Change(s)
02.07.2025	Release of V1.0
22.08.2025	Add step therapy algorithm for Pregnant patients between 10 to 20 weeks

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