



Zofran® (ondansetron) (Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Up to 48 mg daily

B. Max Units (per dose and over time) [HCPCS Unit]:

- Chemotherapy related nausea and vomiting: 48 billable units per day
- All other indications: 4 billable units per day

III. Initial Approval Criteria ¹⁻⁵

Coverage is provided in the following conditions:

Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) †

- Patient is receiving emetogenic anticancer chemotherapy

Prevention of Post-Operative Nausea and/or Vomiting †

Breakthrough Treatment for anticancer Chemotherapy Induced Nausea/Vomiting ‡

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹⁻⁵

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Beneficial response as evidenced by reduction in nausea and/or vomiting; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions (anaphylaxis and bronchospasm), QT prolongation, serotonin syndrome (e.g., mental status changes, autonomic instability, neuromuscular symptoms, etc), myocardial ischemia, etc.

V. Dosage/Administration^{1,3}

Indication	Dose
Prevention of chemotherapy-induced nausea and vomiting (CINV) & Breakthrough treatment for chemotherapy-induced nausea/vomiting	<p>Adults and pediatric patients 1 month and older</p> <ul style="list-style-type: none"> • Administer 0.15 mg/kg intravenously (IV) x 3 doses on the day of chemotherapy, up to a maximum of 16 mg per dose <p>Note: A single maximum daily dose of 8 mg should be used in patients with severe hepatic impairment</p>
Postoperative nausea and vomiting	<p>Adults and pediatric patients 1 month to 12 years and > 40 kg:</p> <ul style="list-style-type: none"> • Administer 4 mg intravenously (IV) given as a single dose <p>Pediatric patients 1 month to 12 years and ≤ 40 kg:</p> <ul style="list-style-type: none"> • Administer 0.1 mg/kg intravenously (IV) given as a single dose

VI. Billing Code/Availability Information

HCPCS Code:

- J2405 – Injection, ondansetron hydrochloride, per 1 mg: 1 billable unit = 1 mg

NDC(s):

- Zofran® injection, 2 mg/mL, 20 mL multi-dose vial: 00173-0442-xx
**Branded product no longer available on market. Generics available from numerous manufacturers.*

VII. References

1. Zofran [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; October 2021. Accessed March 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for ondansetron. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.

4. Roila F, Molassiotis A, Herrstedt J, et al. MASCC and ESMO Consensus Guidelines for the Prevention of Chemotherapy and Radiotherapy-Induced Nausea and Vomiting: ESMO Clinical Practice Guidelines. *Ann Oncol* (2016) 27 (suppl 5): v119-v133.
5. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Guideline Update. *J Clin Oncol*. 2020 Aug 20;38(24):2782-2797. Doi: 10.1200/JCO.20.01296.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
T41.0X5A	Adverse effect of inhaled anesthetics, initial encounter
T41.1X5A	Adverse effect of intravenous anesthetics, initial encounter
T41.205A	Adverse effect of unspecified general anesthetics, initial encounter
T41.295A	Adverse effect of other general anesthetics, initial encounter
T41.45XA	Adverse effect of unspecified anesthetic, initial encounter
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter
T45.95XD	Adverse effect of unspecified primarily systemic and hematological agent, subsequent
T45.95XS	Adverse effect of unspecified primarily systemic and hematological agent, sequela
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.905D	Adverse effect of unspecified drugs, medicaments and biological substances, subsequent
T50.905S	Adverse effect of unspecified drugs, medicaments and biological substances, sequela
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T88.59XA	Other complications of anesthesia, initial encounter
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/ LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC