MEDICA®

Kytril® (granisetron)
(Intravenous)

Document Number: IC-0076

Last Review Date: 04/04/2022
Date of Origin: 12/01/2011
Dates Reviewed: 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 02/2015, 01/2016, 01/2017, 01/2018, 02/2019, 02/2020, 04/2021, 04/2022

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

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

- Granisetron 0.1 mg/mL single-dose vial: 1 vial per day
- Granisetron 1 mg/mL single-dose vial: 1 vial per day
- Granisetron 4 mg/4 mL multi-dose vial: 1 vial per 4 days

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

- 10 billable units per day

III. Initial Approval Criteria[1,2,3,6,7,8]

Coverage is provided in the following conditions:

Prevention of chemotherapy induced nausea and vomiting (CINV) †

- Patient is receiving emetogenic chemotherapy

Prevention & Treatment of post-operative nausea and vomiting in adults†

Breakthrough treatment for chemotherapy-induced nausea/vomiting ‡

Prevention of nausea and vomiting associated with radiation treatment ‡

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

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IV. Renewal Criteria[1,2,3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: gastric or intestinal peristalsis, severe hypersensitivity reactions, QT prolongation, etc.

V. Dosage/Administration[1,2,3,6,7,8]

Indication	Dose
Prevention of chemotherapy-induced nausea and vomiting	Administer 10 mcg/kg intravenously within 30 minutes before initiation of chemotherapy and only on the day(s) chemotherapy is given **OR** Administer 1 mg intravenously (fixed dose) prior to chemotherapy
Postoperative nausea and vomiting	Adults Administer 1 mg intravenously (fixed dose)

VI. Billing Code/Availability Information

HCPCS Code:

- J1626 – Granisetron hydrochloride 100 mcg Injection: 1 billable unit = 100 mcg

NDC*:

- Kytril injection 1 mg/mL; 1 mL single-dose vial: 0004-0239-xx
- Kytril injection 4 mg/4 mL; 4 mL multi-dose vial: 0004-0240-xx
- Kytril injection 0.1 mg/mL; 1 mL single-dose vial 0004-0242-xx (package of 5 single-use vials)

** Branded product no longer available on market. Generics available from numerous manufacturers. Available as single-dose and multi-dose vials.*

VII. References

1. Kytril [package insert]. South San Francisco, CA; Genentech USA, Inc.; April 2011. Accessed March 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for granisetron. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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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 2022.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2022. National Comprehensive Cancer Network, 2022. 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 2022.
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 Clinical Practice Guideline Update. J Clin Oncol. 2017 Oct 1;35(28):3240-3261.
6. Cupissol DR, Serrou B, Caubel M, et al. The efficacy of granisetron as a prophylactic anti-emetic and intervention agent in high-dose cisplatin-induced emesis. Eur J Cancer. 1990;26 Suppl 1:S23-7.
7. Riviere A. Dose finding study of granisetron in patients receiving high-dose cisplatin chemotherapy. The Granisetron Study Group. Br J Cancer. 1994 May;69(5):967-71.
8. Perez EA[1], Navari RM, Kaplan HG, et al. Efficacy and safety of different doses of granisetron for the prophylaxis of cisplatin-induced emesis. Support Care Cancer. 1997 Jan;5(1):31-7.

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

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ICD-10	ICD-10 Description
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T88.59XA	Other complications of anesthesia, initial encounter
Z51.0	Encounter for antineoplastic radiation therapy
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs)may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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 Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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