



## Cinvanti® (aprepitant) (Intravenous)

Document Number: IC-0336

Last Review Date: 10/03/2023

Date of Origin: 11/21/2017

Dates Reviewed: 11/2017, 02/2018, 05/2018, 04/2019, 04/2020, 04/2021, 04/2022, 04/2023, 10/2023

### 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]:

- Cinvanti 130 mg single-dose vial: 1 vial per 7 days

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

- 130 billable units per 7 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

#### Universal Criteria <sup>1</sup>

- Patient is not taking pimozide concurrently; **AND**
- Patient must have failed or experienced intolerable side effects to a fosaprepitant product (e.g., Emend, Fosaprepitant, Focinvez, etc.) prior to consideration of Cinvanti; **AND**

#### Prevention of Chemotherapy induced Nausea and vomiting (CINV) † <sup>1-5</sup>

- Patient is receiving highly and/or moderately emetogenic chemotherapy (see HEC/MEC list below); **AND**
- Must be used in combination with a 5-HT<sub>3</sub> antagonist such as ondansetron, granisetron, palonosetron, etc.; **AND**
- Must be used in combination with a corticosteroid such as dexamethasone

| Highly Emetogenic Chemotherapy (HEC) |            |           |                  |
|--------------------------------------|------------|-----------|------------------|
| Carboplatin                          | Carmustine | Cisplatin | Cyclophosphamide |

|  |                                  |  |   |
|--|----------------------------------|--|---|
| Dacarbazine  | Doxorubicin                      | Epirubicin                             | Fam-trastuzumab<br>deruxtecan-nxki  |
| Ifosfamide   | Mechlorethamine                  | Melphalan $\geq 140$ mg/m <sup>2</sup> | Sacituzumab govitecan-<br>hziy  |
| Streptozocin   |                                  |  |   |
| <b>The following can be considered HEC in certain patients</b> |                                  |  |   |
| Dactinomycin   | Daunorubicin                     | Idarubicin                             | Irinotecan  |
| Methotrexate<br>$\geq 250$ mg/m <sup>2</sup>                   | Oxaliplatin                      | Trabectedin                            |   |
| <b>Moderately Emetogenic Chemotherapy (MEC)</b>                |                                  |  |   |
| Aldesleukin >12-15<br>million IU/m <sup>2</sup>                | Amifostine >300mg/m <sup>2</sup> | Bendamustine                           | Busulfan  |
| Clofarabine  | Cytarabine >200mg/m <sup>2</sup> | Dinutuximab                            | Dual-drug liposomal<br>encapsulation of<br>cytarabine and<br>daunorubicin |
| Irinotecan Liposomal   | Lurbinectedin                    | Melphalan <140 mg/m <sup>2</sup>       | Naxitamab-ggqk  |
| Romidepsin   | Temozolomide                     |  |   |
| <b>The following regimens can be considered HEC</b>            |                                  |  |   |
| FOLFOX   | FOLFIRI                          | FOLFIRINOX;<br>FOLFOXIRI               | AC (any anthracycline +<br>cyclophosphamide)                              |

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

#### IV. Renewal Criteria <sup>1</sup>

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; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, etc.

#### V. Dosage/Administration <sup>1</sup>

| Indication                  | Dose  |
|-----------------------------|---|
| Prevention of chemotherapy- | Administer as either a 30 minute infusion or 2 minute injection<br><u>HEC (Single Dose Regimen)</u> |

|                             |   |
|-----------------------------|---|
| induced nausea and vomiting | – 130 mg intravenously (IV) on Day 1 approximately 30 minutes prior to chemotherapy                                     |
|                             | <u>MEC (3-Day Regimen with oral aprepitant)</u>   |
|                             | – 100 mg IV on Day 1 approximately 30 minutes prior to chemotherapy followed by oral aprepitant (80mg) on Days 2 and 3. |
|                             | <u>MEC (Single-dose Regimen)</u>  |
|                             | – 130 mg IV on Day 1 approximately 30 minutes prior to chemotherapy   |

## VI. Billing Code/Availability Information

### HCPCS Code:

- J0185 – Injection, aprepitant, 1 mg; 1 billable unit = 1 mg

### NDC:

- Cinvanti 130 mg/18 mL injectable emulsion single-dose vial: 47426-0201-xx

## VII. References

1. Cinvanti [package insert]. San Diego, CA; Heron Therapeutics; March 2022. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Aprepitant. National Comprehensive Cancer Network, 2023. 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. March 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2023. National Comprehensive Cancer Network, 2023. 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 2023.
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  |
| 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 encounter   |
| 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 encounter |
| T50.905S | Adverse effect of unspecified drugs, medicaments and biological substances, sequela              |
| 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: <https://www.cms.gov/medicare-coverage-database/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 GBA, LLC                                 |
| M (11)  | NC, SC, WV, VA (excluding below)       | Palmetto GBA, LLC                                 |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |  |
|---|---|--|
| Jurisdiction  | Applicable State/US Territory   | Contractor                               |
| 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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PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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Fax: 763.847.4010  
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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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