

Cinvanti™ (aprepitant) (Intravenous)

Document Number: IC-0336

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Date of Origin: 11/21/2017

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

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]:

- Cinvanti 130 mg vial injection: 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^{1,2,3,4,5}

Coverage is provided in the following conditions:

- Patient is age of 18 years or older; **AND**

Universal Criteria

- Patient is not taking pimozide concurrently; **AND**

Prevention of Chemotherapy induced Nausea and vomiting (CINV) †

- Patient is receiving highly and/or moderately emetogenic chemotherapy (see HEC/MEC list below); **AND**
- Must be used in combination with a 5-HT₃ 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 | Ifosfamide |
| Mechlorethamine | Streptozocin | Melphalan | Sacituzumab govitecan |
| The following chemotherapy can be considered HEC in certain patients: | | | |
| Dactinomycin | Irinotecan | Oxaliplatin | Methotrexate ≥250mg/m ² |

| | | | |
|--|----------------------------------|----------------------------------|--|
| Daunorubicin | Trabectedin | Idarubicin | |
| Moderately Emetogenic Chemotherapy (MEC) | | | |
| Aldesleukin >12-15 million IU/m ² | Amifostine >300mg/m ² | Azacitidine | Bendamustine |
| Busulfan | Clofarabine | Cytarabine >200mg/m ² | Daunorubicin Liposomal; Cytarabine Liposomal |
| Dinutuximab | Fam-trastuzumab deruxtecan | Irinotecan Liposomal | Lurbinectedin |
| Temozolomide | | | |
| The following regimens can be considered HEC: | | | |
| FOLFOX | FOLFIRI | FOLFIRINOX; FOLFOXIRI | AC (any anthracycline + cyclophosphamide) |

† FDA-approved indication(s)

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

V. Dosage/Administration

| Indication | Dose |
|--|--|
| Prevention of chemotherapy-induced nausea and vomiting | Administer as either a 30 minute infusion or 2 minute injection |
| | <u>HEC (Single Dose Regimen)</u> |
| | – 130 mg intravenously (IV) Day 1 approximately 30 minutes prior to chemotherapy |
| | <u>MEC (3-Day Regimen with oral aprepitant)</u> |
| | – 100 mg IV 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 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; October 2019. Accessed February 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Aprepitant. National Comprehensive Cancer Network, 2021. 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. February 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2021. National Comprehensive Cancer Network, 2020. 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 February 2021.
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.

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 |
| T45.1X5S | 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 |
| 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): 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 |
| 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 |