Clinical Policy: Aprepitant (Emend, Cinvanti), Fosaprepitant (Emend for injection)

Reference Number: LA.PMN.19
Effective Date:
Last Review Date: 01.21
Line of Business: Medicaid

Coding Implications Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Aprepitant (Emend®, Cinvanti®) and Fosaprepitant (Emend® for injection) are substance P/neurokinin 1 (NK_1) receptor antagonists.

FDA Approved Indication(s)

Emend and Cinvanti are indicated:

- **In combination with other antiemetic agents for patients 6 months of age and older (*Emend injection*) or 18 years of age and older (*Cinvanti*), for prevention of:**
  - **Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin**
  - **Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)**
- **For prevention of delayed nausea and vomiting associated with initial and repeat courses of MEC as a single-dose regimen (*Cinvanti only*)**

Limitation(s) of use:

- **Emend and Cinvanti have not been studied for treatment of established nausea and vomiting.**
- **Chronic continuous administration of Emend is not recommended.**

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Emend and Cinvanti are medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Prevention of Nausea and Vomiting Associated with Cancer Chemotherapy (must meet all):

1. **Prescribed for the prevention of chemotherapy-induced nausea/vomiting;**
2. **Member meets one of the following (a, b, or c):**
   a. **Emend injection: age ≥ 6 months;**

b. **Cinvanti: age ≥ 18 years;**

3. **Member is scheduled to receive moderately to highly emetogenic cancer chemotherapy (*see Appendix D*);**
4. **Prescribed in combination with a serotonin (5-HT_3) receptor antagonist and dexamethasone;**
5. **Dose does not exceed:**
   a. **Emend for injection: 150 mg on Day 1;**
   b. **Cinvanti: 130 mg on Day 1 for HEC and MEC (single-dose regimen), or 100 mg on Day 1 for MEC (3-day regimen).**

Approval duration:
Medicaid – Projected duration of chemotherapy

B. Other diagnoses/indications

1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Prevention of Nausea and Vomiting Associated with Cancer Chemotherapy (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy;**
3. **Member continues to receive moderately to highly emetogenic cancer chemotherapy (*see Appendix D*);**
4. **Prescribed in combination with a 5-HT_3 receptor antagonist and dexamethasone;**
5. **If request is for a dose increase, new dose does not exceed:**
   a. **Emend for injection: 150 mg on Day 1;**
   b. **Cinvanti: 130 mg on Day 1 for HEC and MEC (single-dose regimen), or 100 mg on Day 1 for MEC (3-day regimen).**

Approval duration:
Medicaid – Projected duration of chemotherapy

B. Other diagnoses/indications (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 12 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-HT$_3$: serotonin 5-hydroxytryptamine, type 3
ASCO: American Society of Clinical Oncology
FDA: Food and Drug Administration
HEC: highly emetogenic cancer chemotherapy
MEC: moderately emetogenic cancer chemotherapy
NCCN: National Comprehensive Cancer Network
NK$_1$: neurokinin 1
PONV: postoperative nausea and vomiting

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
5-HT$_3$ Serotonin Antagonists		
granisetron (Kytril®)	Prevention of PONV* 0.35 to 3 mg (5 to 20 mcg/kg) IV at the end of surgery	20 mcg/kg/dose
ondansetron (Zofran®, Zofran® ODT)	Prevention of PONV 16 mg PO given 1 hr prior to anesthesia or 4 mg IM/IV as a single dose given 30 min before end of anesthesia	PO: 16 mg/dose IV: 4 mg/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
****Off-label***

Appendix C: Contraindications/Boxed Warnings

- **Contraindication(s): known hypersensitivity, concurrent use with pimozide**
- **Boxed warning(s): none reported**

Appendix D: American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) Recommendations in Oncology

- **Minimal emetic risk chemotherapy: No routine prophylaxis is recommended.**
- **Low emetic risk chemotherapy: Recommended options include dexamethasone (recommended by both ASCO and NCCN) or metoclopramide, prochlorperazine, or a 5-HT$_3$ receptor antagonist (recommended by NCCN only). NK$_1$ receptor antagonists are not included in low risk antiemetic recommendations.**

- **Moderate emetic risk chemotherapy: 5-HT_3 receptor antagonists and dexamethasone may be used in combination and with or without NK_1 receptor antagonists. Olanzapine may also be used in combination with palonosetron and dexamethasone.**
  - **Examples of moderate emetic risk chemotherapy: azacitidine, alemtuzumab, bendamustine, carboplatin, clofarabine, cyclophosphamide < 1,500 mg/m^2, cytarabine < 1,000 mg/m^2, daunorubicin, doxorubicin, epirubicin, idarubicin, ifosfamide, irinotecan, oxaliplatin**
- **High emetic risk chemotherapy: NK_1 receptor antagonists are recommended for use in combination with 5-HT_3 receptor antagonists and dexamethasone. Olanzapine may also be used in combination with 5-HT_3 receptor antagonists, dexamethasone, and/or NK_1 receptor antagonists.**
  - **Examples of high emetic risk chemotherapy: carmustine, cisplatin, cyclophosphamide ≥ 1,500 mg/m^2, dacarbazine, dactinomycin, mechlorethamine, streptozocin**
- **Breakthrough emesis: Per NCCN, an agent from a different drug class is recommended to be added to the current antiemetic regimen. Drug classes include atypical antipsychotics (olanzapine), benzodiazepines (lorazepam), cannabinoids (dronabinol, nabilone), phenothiazines (prochlorperazine, promethazine), 5-HT_3 receptor antagonists (dolasetron, ondansetron, granisetron), steroids (dexamethasone), or (haloperidol, metoclopramide, scopolamine). An NK_1 receptor antagonist may be added to the prophylaxis regimen of the next chemotherapy cycle if not previously included.**

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Cinvanti® (aprepitant)	Prevention of chemotherapy-induced nausea and vomiting	*HEC or MEC (single-dose regimen):* 130 mg IV on Day 1 *MEC (3-day regimen):* 100 mg IV on Day 1	Single-dose: 130 mg/dose 3-day regimen: 100 mg/dose

VI. Product Availability

- **Emend for injection single-dose vial, powder for reconstitution: 150 mg**
- **Cinvanti single-dose vial, injectable emulsion: 130 mg/18 mL**

VII. References

1. **Emend Prescribing Information. Whitehouse Station, NJ: Merck & Company, Inc.: October 2020. Available at: http://www.emend.com. Accessed November 13, 2020.**
2. **Cinvanti Prescribing Information. San Diego, CA: Heron Therapeutics, Inc.; October 2019. Available at: http://www.cinvanti.com. Accessed November 13, 2020.**

3. **Hesketh, PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2017: JCO2017744789.**
4. **National Comprehensive Cancer Network. Antiemesis Version 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 13, 2020.**
5. **Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/.**
6. **Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 13, 2020.**

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1453	Injection, fosaprepitant, 1 mg
J0185	Injection, aprepitant, 1 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	01.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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