



Medicare Part C Medical Coverage Policy

Oral Antiemetic Medications

Origination: June 17, 2009
Review Date: May 15, 2019
Next Review: May, 2021

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Oral antiemetic medications covered in this policy are used to prevent nausea and vomiting caused by anticancer (chemotherapy) drugs, radiation therapy and surgery. They are in a class of medications called antiemetics and include 5-HT₃ receptor antagonists and oral NK-1 antagonists. Antiemetics work by blocking the action of serotonin, a natural substance that may cause nausea and vomiting or by blocking the action of neurokinin, a natural substance in the brain that causes nausea and vomiting.

POLICY STATEMENT

Coverage will be provided for oral antiemetic medications when it is determined to be medically necessary and when the medical criteria and guidelines shown below are met.

Refer to the Oral Anticancer Medications medical policy for information on coverage of antiemetic medications used in conjunction with oral anticancer medications.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

PART B COVERAGE CRITERIA:

- A. Preauthorization by the Plan may be required;
Must meet all the specified criteria noted in B and C.
- B. Oral antiemetic medications are covered if all the following criteria **(1-4)** are met:
1. The drug has been approved by the Food & Drug Administration (FDA) for use as an antiemetic,
AND
 2. The drug has been ordered by the treating physician as part of a cancer chemotherapy regimen,
AND
 3. The drug is used as a full therapeutic replacement for an intravenous (IV) antiemetic drug that would otherwise have been administered at the time of chemotherapy treatment, (please see below for when coverage will not be approved)
AND
 4. Oral antiemetic drugs administered with a particular chemotherapy treatment must be initiated within two hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed forty-eight (48) hours from that time.
- C. The use of the oral antiemetic 3-drug combined regimen consisting of an NK-1 antagonist, a 5HT3 antagonist when given with dexamethasone are covered under Part B only if, **all of the criteria #1-4 listed above** are met, all 3 drugs are given together as part of an oral antiemetic drug regimen, and are administered when the member is receiving one or more of the following anti-cancer chemotherapeutic agents noted in item 5.
1. There are only three NK-1 antagonists approved for this use, Emend (aprepitant) J8501, (rolapitant) J8670 and (netupitant /palonosetron) when given with dexamethasone J8540.
 2. Emend (aprepitant) or rolapitant is covered when given as part of a 3-drug regimen which includes a 5HT3 antagonist and dexamethasone.
 3. (netupitant/palonosetron) is covered when given with

dexamethasone. A separate 5HT3 antagonist is not needed.

4. Examples of 5-HT3 antagonists include Kytril (granisetron), Zofran (ondasetron), or Anzamet (dolasetron)
5. Oral antiemetic 3-drug combination covered when the member is receiving one or more of the following anti-cancer chemotherapy agents:
 - Alemtuzumab
 - Azacitidine
 - Bendamustin
 - Carboplatin
 - Carmustine
 - Cisplatin
 - Clofarabine
 - Cyclophosphamide
 - Cytarabine
 - Dacarbazine
 - Daunorubicin
 - Doxorubicin
 - Epirubicin
 - Idarubicin
 - Ifosfamide
 - Irinotecan
 - Lomustine
 - Mechlorethamine
 - Oxaliplatin
 - Streptozocin

WHEN COVERAGE WILL NOT BE APPROVED UNDER PART B BENEFIT

1. When any of the above criteria are not met.
2. Criterion #B-3 above is not met when the chemotherapy drug is an oral drug or when the chemotherapy drug is administered intravenously in the home setting because the type and dosage of chemotherapy drugs administered in these settings do not require intravenous antiemetic drugs.
3. Doses of oral antiemetic drugs not used as part of the 3-drug regimen noted above.

PART D COVERAGE CRITERIA:

A. Preauthorization by the Plan is required;

1. If the above criteria are not met for coverage under the Part B benefit, the medication may be covered under Part D if:
 - a. The medication is administered for an FDA approved use;
 - b. The medication is on a prescription from a physician;
 - c. The medication is used and sold in the United States

- d. The medication is used for a medically accepted indication.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: J8501, J8540, J8650, J8670, Q0161, Q0163, Q0162, Q0164, Q0166, Q0167, Q0169, Q0173, Q0174, Q0175, Q0177, Q0180, Q0511, Q0512, J8655.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

1. If the above criteria (B1-4) are met, the quantity of oral antiemetic drugs covered for each episode of chemotherapy cannot exceed the initial loading dose plus 48 hours of therapy. However, for the drugs granisetron (Q0166) and dolasetron (Q0180), the quantity of drugs covered for each episode of chemotherapy is limited to the initial loading dose plus 24 hours of therapy. Quantities of drugs in excess of these amounts are non-covered.
2. More than one oral antiemetic drug may be covered for concurrent use if more than one oral drug is needed to fully replace the intravenous drugs that would otherwise have been given.

References:

1. Decision Memo for Aprepitant for Chemotherapy-Induced Emesis (CAG-00248R) Date: May 29, 2013; Accessed online at <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=264> on 05/15/19.
2. Medicare Local Coverage Article for Oral Antiemetic Drugs – CGS Administrator (A52480); Effective date: 10/01/2015; accessed via <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> 05/15/19.
3. Medicare Local Coverage Determination for Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) - CGS (L33827); Effective Date 1/1/2016; viewed via www.cgsmedicare.com on 05/15/19.
4. Medicare Local Coverage Article for Oral Anticancer Drugs (A52479); Effective 10/01/2015; accessed via Internet site <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11559&ContrID=140> on 05/15/19.
5. CGS DME MAC Publication. May 28, 2015: New Oral Antiemetic Drug Akynzeo – Coverage and Coding-Revised, accessed online at <http://cgsmedicare.com/jc/pubs/news/2015/0515/cope29368.html>, on 05/15/19.
6. CGS DME MAC Publication. July 23, 2015: LCD and Policy Article Revisions Summary – Removed drug name Akynzeo from policy article (A52480), accessed online <http://cgsmedicare.com/jc/pubs/news/2015/0715/cope29892.html> on 5/15/19.
7. CGS DME MAC Publication. November 19, 2015: New Oral Antiemetic Drug Varubi-Coverage and Coding Revised accessed online at <http://cgsmedicare.com/jc/pubs/news/2016/0516/cope32967.html> on 5/15/19.

Policy Implementation/Update Information:

Revision Date: New Policy June 2007, October 20, 2011; Added language to Part B coverage criteria to be consistent with Medicare LCD.

Revision Date: June 17, 2013: updated policy according to Decision Memo; Added Moderately chemotherapy agents; Deleted the note regarding Part D criteria.

Revision Date: June, 2014; CGS LCD (L11560) updated revision effective 01/01/2014, added code Q0161 and deleted code Q0165, Q0168, Q0170, Q0171, Q0172, Q0176 and Q0178; Policy reviewed June 2013 and updated next review for June, 2015.

Revision Date: June 7, 2015: Annual Review; under Part B Coverage Criteria, item C added new reference to Akynzeo coverage per LCD L11560; added codes Q0162 per LCD L11560 and Q9978 per CGS publication for revised code. October 29, 2015 updated LCD due to ICD-10 update only. December 16, 2015 Coding update only.

Medical Coverage Policy: Oral Antiemetic Medications

Revision Date: February 2016: Review performed for staff clarification – Title name change to Oral Antiemetic Medications for continuity with the LCD. Policy Statement: Added statement referencing the Oral Anticancer medical policy for coverage information of antiemetic medications used in conjunction with oral anticancer medications, for continuity with CMS guidance. Indications For Coverage: Revised to identify specific coverage for oral antiemetic medications and for antiemetic 3-drug combined regimen as outlined in noted LCD and Article. Akynzeo was removed from LCD L33827, therefore removed from the policy. Moved item D - reference to antiemetic medications used with oral anticancer drugs to the Oral Anticancer Medications medical policy for continuity of CMS guidance. Updated references.

Revision Date: July 20, 2016; Review performed due to CGS notification of New Oral Antiemetic Drug Varubi. Indications For Coverage C.1 Updated “two” to “three”, added rolapitant Q0181, and removed Q9978 C.2 “or rolapitant” added to make consistent with LCD. Updated References.

Revision Date: May 17, 2017: Indications for Coverage: Part B Coverage Criteria C.1 changed Q0181 to J8670; Coding Section: Added J8670.

Revision Date: May 15, 2019; Annual Review. No CMS Updates. Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee: May 15, 2019

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator