

Clinical Policy: Dolasetron (Anzemet)

Reference Number: HIM.PA.85

Effective Date: 12/14

Last Review Date: 08/17

Line of Business: Health Insurance Marketplace

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Dolasetron (Anzemet<sup>®</sup>) is a selective serotonin 5-HT<sub>3</sub> receptor antagonist that serves as an antiemetic and anti-nausea agent.

### **FDA Approved Indication**

Anzemet is indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older.

Limitation of use: Dolasetron has been associated with dose-dependent cardiovascular safety concerns such as QT, PR, and QRS interval prolongation and torsade de pointes.

### **Policy/Criteria**

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

#### **I. Initial Approval Criteria**

##### **A. Chemotherapy-induced Nausea/Vomiting Prophylaxis (must meet all):**

1. Prescribed for prevention of chemotherapy-induced nausea/vomiting;
2. Failure of ondansetron or granisetron at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 100 mg/dose (1 tablet/dose).

**Approval duration: Duration of chemotherapy or 12 months (whichever is less)**

##### **B. Other diagnoses/indications**

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### **II. Continued Therapy**

##### **A. Chemotherapy-induced Nausea/Vomiting Prophylaxis (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation supports that member is currently receiving chemotherapy;
3. Documentation of response to therapy;
4. If request is for a dose increase, new dose does not exceed 100 mg/dose (1 tablet/dose).

**Approval duration: Duration of chemotherapy or 12 months (whichever is less)**

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**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 – HIM.PA.21 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

**V. References**

1. Anzemet Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; September 2013. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/020623s010lbl.pdf,020624s023lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020623s010lbl.pdf,020624s023lbl.pdf). Accessed April 7, 2017.
2. Hesketh PJ, Bohlke K, Lyman GH et al. Antiemetics: American society of clinical oncology focused guideline update. J Clin Oncol. 2016 Feb 1; 34(4):381-6. doi: 10.1200/JCO.2015.64.3635.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed January 2017.
4. Basch E, Prestrud AA, Hesketh PJ et al. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2011 Nov 1;29(31):4189-98.doi: 10.1200/JCO.2010.34.4614. Epub 2011 Sep 26.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformatted guideline to new format. Added Workflow reference document.	12/15	12/15
Modified description to indicate that the policy applies only to the oral formulation as the injectable formulation is no longer available. Removed metoclopramide, nabilone, and dronabinol as acceptable formulary alternatives that could be trial per the American Society of Clinical Oncology clinical practice guideline recommendation for the use 5-hydroxytryptamine-3 (5-HT3) receptor antagonist use as the preferred antiemetic for CINV. Updated trial and failure wording to include maximum indicated doses, unless member experiences clinically	09/16	11/16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
significant adverse effect or contraindication(s). Modified length of initial and continued approval to include duration of chemotherapy or 12 months, whichever is less; Updated references.		
Converted to new template Added FDA approved indication Changed requirement of a trial of both ondansetron and granisetron to a trial of one or the other. The American Society of Clinical Oncology clinical practice guideline states that there is equivalency between ondansetron and granisetron.	04/17	08/17

**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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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