

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

CESAMET
(nabilone)

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

Ref # 48-J

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

FDA-APPROVED INDICATIONS

Cesamet is indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. This restriction is required because a substantial proportion of any group of patients treated with Cesamet can be expected to experience disturbing psychotomimetic reactions not observed with other antiemetic agents.

Because of its potential to alter the mental state, Cesamet is intended for use under circumstances that permit close supervision of the patient by a responsible individual particularly during initial use of Cesamet and during dose adjustments.

Cesamet contains nabilone, which is controlled in Schedule II of the Controlled Substance Act. Schedule II substances have a high potential for abuse. Prescriptions for Cesamet should be limited to the amount necessary for a single cycle of chemotherapy (i.e., a few days).

Cesamet is not intended to be used on an as needed basis or as a first antiemetic product prescribed for a patient.

As with all controlled drugs, prescribers should monitor patients receiving Cesamet for signs of excessive use, abuse and misuse. Patients who may be at an increased risk for substance abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse) or mental illness.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for nausea and vomiting associated with cancer chemotherapy.
- AND**
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE of the following anti-emetic agents: A) dexamethasone, B) metoclopramide, C) olanzapine, D) promethazine, E) prochlorperazine, or F) oral 5-HT₃ receptor antagonists (e.g., ondansetron, granisetron, Anzemet [dolasetron])

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Cesamet is indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. This restriction is required because a substantial proportion of any group of patients treated with Cesamet can be expected to experience disturbing psychotomimetic reactions not observed with other antiemetic agents. Cesamet is a controlled substance with a high potential for abuse.

Cesamet_QL_ALL_Rx

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The usual adult dose of Cesamet is 1 mg or 2 mg twice a day. On the day of chemotherapy, the initial dose should be given one to three hours before the chemotherapeutic agent is administered. To minimize side effects, it is recommended that the lower starting dose be used and that the dose be increased as necessary. A dose of 1 mg or 2 mg the night before may be useful. The maximum recommended daily dose is 6 mg given in divided doses three times a day. Cesamet may be administered two or three times daily during the entire course of each cycle of chemotherapy and, if needed, for 48 hours after the last dose of each cycle of chemotherapy.

Cesamet is not intended to be used on an as needed basis or as a first antiemetic product prescribed for a patient. Per guidelines by the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO), Cesamet is only recommended for use when patients experience nausea and vomiting despite optimal prophylaxis with conventional or first-line antiemetic therapies. Therefore, patients must have tried at least one conventional therapy (dexamethasone, metoclopramide, olanzapine, promethazine, prochlorperazine, or oral 5-HT3 receptor antagonists).^{4,5} The post limit quantity of approval is set at 54 capsules per month to allow for at least three chemotherapy cycles per month.

REFERENCES

1. Cesamet [package insert]. Somerset, New Jersey: Meda Pharmaceuticals Inc.; May 2015.
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4. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Onc* 2017; 35:3240-3261.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. V.3.2018. Available at: www.nccn.org. Accessed January 2019.

Written by: UM Development (CT)
 Date Written: 05/2006
 Revised: (NB) 09/2006, 09/2007, 04/2008, 03/2009; (KD) 03/2010; (MS) 04/2011, 02/2012, 01/2013, 01/2014, 01/2015, (LN) 04/2015 (Denial Reasons); (MS) 01/2016, 01/2017; (DS) 01/2018, 01/2019 (no clinical changes)
 Reviewed: Medical Affairs: (MM, MD) 05/2006; (WF, MD) 09/2007, 04/2008, 03/2009, 03/2010; (KP) 04/2011, 02/2012; (LS) 01/2013; (KP) 01/2014; (DC) 01/2015; (LS) 01/2016; (ME) 01/2017; (DC) 01/2018
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for nausea and vomiting associated with cancer chemotherapy?	Yes	No
2	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to at least one of the following anti-emetic agents: A) dexamethasone, B) metoclopramide, C) olanzapine, D) promethazine, E) prochlorperazine, F) oral 5-HT3 receptor antagonists (e.g., ondansetron, granisetron, Anzemet [dolasetron])?	Yes	No
3	Does the patient require use of MORE than 54 capsules per month of Cesamet (nabilone)?	Yes	No

[RPh Note: If yes, then deny and enter a partial approval of 54 capsules per 21 days.]

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 2	Deny	<p>You do not meet the requirements of your plan. Your plan covers additional quantities of this drug when you have nausea and vomiting after taking chemotherapy. Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>
2.	Go to 3	Deny	<p>You do not meet the requirements of your plan. Your plan covers additional quantities of this drug when you meet this condition: -You have tried at least 1 of the following drugs [dexamethasone, metoclopramide, olanzapine, promethazine, prochlorperazine, oral 5-HT3 antagonist (ondansetron, granisetron, Anzemet (dolasetron))] for nausea first and it either did not work for you or you cannot use it. Your request has been denied based on the information we have.</p> <p>[Short Description: No trial of alternatives]</p>
3.	Deny	Approve, 6 months 54 capsules per 21 days*	<p>You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 54 capsules/28 days of Cesamet (nabilone). You have been approved for the maximum quantity that your plan covers for a duration of 6 months. Your request for additional quantities of the requested drug and strength has been denied.</p> <p>[Short Description: Over max quantity]</p>

*** This drug is indicated for short-term acute use; therefore, the mail limit will be the same as the retail limit.**
 The duration of 21 days is used for a 28-day fill period.