# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**
**(generic)**

**CESAMET**
**(nabilone)**

***Status: CVS Caremark Criteria***
***Type: Post Limit Prior Authorization***

## POLICY

### FDA-APPROVED INDICATIONS

Cesamet capsules are 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 capsules are 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 failed to respond adequately to a conventional antiemetic treatment
  [Note: Examples of conventional antiemetic treatments include dexamethasone, metoclopramide, olanzapine, prochlorperazine, and 5-HT3 receptor antagonists (e.g., Anzemet [dolasetron], granisetron, ondansetron)]

Quantity Limits apply.

### POST LIMIT QUANTITY

54 capsules / 21 days*

** The duration of 21 days is used for a 28-day fill period to allow time for refill processing.*

**** These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.***

### REFERENCES

1. Cesamet [package insert]. Bridgewater, NJ: Bausch Health US LLC; March 2020.

 

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3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed January 2021.
4. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2017;35:3240-61.
5. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Antiemesis. V.1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed January 2021.
6. American Society of Clinical Oncology. Understanding Chemotherapy. https://www.cancer.net/navigating-cancer-care/how-cancer-treated/chemotherapy/understanding-chemotherapy. May 2019. Accessed January 2021.
7. American Cancer Society. How is Chemotherapy Used to Treat Cancer? https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-is-chemotherapy-used-to-treat-cancer.html. November 2019. Accessed January 2021.