PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

CESAMET
(nabilone)

Status: CVS Caremark Criteria
Type: Post Limit Prior Authorization

Policy

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: dexamethasone, metoclopramide, olanzapine, promethazine, prochlorperazine, or oral 5-HT3 receptor antagonists.

Quantity Limits apply.

POST LIMIT QUANTITY FOR APPROVAL
54 capsules/21 days* for 6 months
**** 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.

REFERENCES

1. Cesamet [package insert]. Somerset, New Jersey: Meda Pharmaceuticals Inc.; May 2015.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January 2018.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 2018.
4. Hesketh PJ, Bohlke K, Lyman GH, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Onc* 33; 2015; 1-8.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. V.2.2017. Available at: www.nccn.org. Accessed January 2018.