



Prior Authorization Approval Criteria

Cesamet (nabilone)

Generic name: Nabilone

Brand name: Cesamet

Medication class: Cannabinoid

FDA-approved use: Treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Available dosage form: 1 mg capsules

Usual dose range: 1 mg twice daily given 1 to 3 hours prior to chemotherapy on days when chemotherapy is administered. The dose may be increased to a maximum of 2 mg three times a day.

Duration of therapy: For the duration of chemotherapy

Approximate cost: \$400.00 (each bottle contains 20 pills)
(based on AWP 2006)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Patient must be receiving chemotherapy.
- Intolerant or refractory to first-line agents such as Zofran and Emend.
- Patient must be under close supervision during the initial use and during dose adjustments due to its potential for altered mental status.
- The number of pills approved will be limited to the amount necessary for a single cycle of chemotherapy.

Cautions:

- The effects of Cesamet may persist for a variable and unpredictable period of time following its oral administration. Adverse psychiatric reactions can persist for 48-72 hours following cessation of treatment.
- Patients can be expected to experience disturbing psychomimetic reactions not observed with other antiemetic agents.

Contraindications:

- Hypersensitivity to any cannabinoid.

Not approved if:

- Does not meet the above-stated criteria
- Has any contraindications to the use of Cesamet.

Special considerations: Schedule II controlled substance. Comparison to Marinol:

	Cesamet	Marinol
Schedule	II	III
Refrigeration	No	Yes
Abuse potential	Low compared to smoked cannabis	Low compared to smoked cannabis
Dose frequency	Twice daily (usually)	Three-four times a day
Cost per pill	1 mg capsule is \$20.00	2.5 mg \$6.00 5 mg \$12.00
Cost per day	\$40-\$120	10 mg \$22.00 \$18-\$92

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/13/06