

Policies Repository



Policy Title Nabilone (Cesamet®)

Policy Number FS.CLIN.5

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Nabilone (Cesamet®)** is indicated for chemotherapy-induced nausea and vomiting to treat individuals who fail to respond adequately to other antiemetic agents.

The use of nabilone (Cesamet®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Nabilone (Cesamet®) is a synthetic cannabinoid, anti-emetic drug used to control the nausea and vomiting in individuals receiving cancer chemotherapy. Similar to a delta-9-tetrahydrocannabinol (the active principal of marijuana), nabilone (Cesamet®) is a dibenzo(b,d)pyrans. A ketone group at position 9 of the dibenzopyran nucleus and a dimethyl heptyl side chain are believed to be responsible for the differing pharmacologic profiles of nabilone (Cesamet®) and delta-9-tetrahydrocannabinol. In both animal and human studies, nabilone (Cesamet®) has demonstrated an anxiolytic activity. However, the anxiolytic effects of nabilone (Cesamet®) 2 mg were mild as compared to those produced with diazepam 5 mg. Nabilone (Cesamet®) has a restrictive indication for the treatment of 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 nabilone (Cesamet®) can be expected to experience disturbing psychotic alterations of behavior and personality not observed with other antiemetic agents.

Policy Guideline Inclusion

Nabilone (Cesamet®) is approved when **all** of the following inclusion criteria are met:

- Documentation of chemotherapy-induced nausea and vomiting
- Documentation of trial and failure of ondansetron containing product (Zofran®) and one of the following: granisetron HCL (Kytril®) or aprepitant (Emend®)

Policy Guideline Exclusion

Nabilone (Cesamet®) is denied when **any** of the following exclusion criteria are present:

- No documentation of chemotherapy-induced nausea and vomiting

- No documentation of trial and failure of ondansetron containing product (Zofran®) and one of the following: granisetron HCL (Kytril®) or aprepitant (Emend®)

Policy List of Applicable Drugs

Brand Name	Generic Name
Cesamet	Nabilone

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Cesamet® (nabilone capsules). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed June 2, 2009.

Cesamet® (nabilone capsules). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed June 2, 2009.

Cesamet® (nabilone capsules) [package insert]. Costa Mesa, CA: Valeant Pharmaceuticals International; 2009. Also available online at: <http://www.valeant.com/fileRepository/products/PI/cesamet.pdf>. Accessed June 2, 2009.

Policy Link to Related Policies

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