

Title: dronabinol (Marinol)

Origination: 07/28/10	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Dronabinol is an orally active cannabinoid which, like other cannabinoids, has complex effects on the central nervous system (CNS), including central sympathomimetic activity. Cannabinoid receptors have been discovered in neural tissues. These receptors may play a role in mediating the effects of dronabinol and other cannabinoids.
- Marinol is indicated for the treatment of: anorexia associated with weight loss in Members with AIDS; and nausea and vomiting associated with cancer chemotherapy in Members who have failed to respond adequately to conventional antiemetic treatments.
- The recommended dose for:
 - **Appetite Stimulation:** Initially, 2.5 mg Marinol capsules should be administered orally twice daily, before lunch and supper;
 - **Antiemetic:** Marinol is best administered at an initial dose of 5 mg/m², given one (1) to three (3) hours prior to the administration of chemotherapy, then every two (2) to four (4) hours after chemotherapy is given, for a total of four (4) to six (6) doses daily.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Procedure:

- 1.0 Request for *initiation of therapy* with **Marinol** for **refractory nausea and vomiting associated with chemotherapy** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying:
 - 1.1 Member has tried and failed conventional antiemetics (e.g., Phenergan, Compazine, Zofran) and Dexamethasone;
 - 1.2 If criteria are met, Marinol is approvable for three (3) months.
- 2.0 Request for *initiation of therapy* with **Marinol** for **AIDS Wasting, AIDS cachexia, or anorexia associated with AIDS** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying:
 - 2.1 Member has had a trial and failure of Megestrol;
 - 2.2 If criteria are met, Marinol is approvable for three (3) months.

References:

1. Marinol Prescribing Information. Unimed Pharmaceuticals, Inc. Marietta, GA. Revised October 2006.
2. Monthly Prescribing Reference, November 2006.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.