PRIOR AUTHORIZATION POLICY

POLICY: Dronabinol Products Prior Authorization with Step Therapy Policy
- Marinol® (dronabinol capsules – ThePharmaNetwork, generic)
- Syndros® (dronabinol oral solution – Insys/Benuvia)

REVIEW DATE: 12/11/2024

OVERVIEW

Dronabinol capsules and Syndros are cannabinoids indicated for the following uses:1,2
Anorexia associated with weight loss, in patients with Acquired Immune Deficiency Syndrome (AIDS).
Nausea and vomiting associated with cancer chemotherapy, in patients who have failed to respond adequately to conventional antiemetic treatments.

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines regarding the treatment of emesis (version 2.2024 – September 27, 2024) include various antiemetic regimens depending upon the emetogenic potential of the chemotherapy agent(s) being administered.3 For breakthrough emesis, the guidelines recommend adding an agent from a different drug class to the current regimen, but no preference is given among specific products. Dronabinol is included in the list of medications for the treatment of refractory nausea or emesis. Other recommended agents for breakthrough nausea or emesis include serotonin receptor antagonists, olanzapine, lorazepam, haloperidol, metoclopramide, scopolamine, prochlorperazine, promethazine, and dexamethasone. The guidelines also note that dronabinol capsules are not bioequivalent to the oral solution.

Policy Statement
Prior Authorization is recommended for prescription benefit coverage of dronabinol products. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

Recommended Authorization Criteria

Coverage of dronabinol capsules is recommended in those who meet one of the following criteria:

FDA-Approved Indications

Anorexia Associated with Weight Loss in a Patient with Acquired Immune Deficiency Syndrome (AIDS). Approve for 6 months if the patient meets ONE of the following (A or B):
Generic dronabinol capsules are requested; OR
If brand Marinol is prescribed, the patient meets BOTH of the following (i and ii):
Patient has tried generic dronabinol capsules; AND
The Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Nausea and Vomiting Associated with Cancer Chemotherapy. Approve for 1 year if the patient meets BOTH of the following (A and B):
Patient has failed to respond adequately to at least TWO conventional antiemetic treatments; AND
Note: Examples of conventional antiemetic treatments include selective serotonin [5-HT3] receptor antagonists (such as ondansetron, granisetron, Anzemet [dolasetron], Aloxi [palonosetron injection]), Akynzeo

(netupitant/palonosetron capsules), Emend (aprepitant capsules), Varubi (rolapitant tablets), metoclopramide, prochlorperazine, dexamethasone, olanzapine.
Patient meets ONE of the following (i or ii):
Generic dronabinol capsules are requested; OR
If brand Marinol is prescribed, the patient meets BOTH of the following (a and b):
Patient has tried generic dronabinol capsules; AND
The Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Coverage of Syndros is recommended in those who meet one of the following criteria:

FDA-Approved Indications

Anorexia Associated with Weight Loss in a Patient with Acquired Immune Deficiency Syndrome (AIDS). Approve for 6 months if the patient meets ONE of the following (A or B):
Patient has tried generic dronabinol capsules; OR
Patient cannot swallow or has difficulty swallowing capsules.

Nausea and Vomiting Associated with Cancer Chemotherapy. Approve for 1 year if the patient meets BOTH of the following (A and B):
Patient has failed to respond adequately to at least TWO conventional antiemetic treatments; AND
Note: Examples of conventional antiemetic treatments include selective serotonin [5-HT3] receptor antagonists (such as ondansetron, granisetron, Anzemet [dolasetron], Aloxi [palonosetron injection]), Akynzeo (netupitant/palonosetron capsules), Emend (aprepitant capsules), Varubi (rolapitant tablets), metoclopramide, prochlorperazine, dexamethasone, olanzapine.
Patient meets ONE of the following (i or ii):
Patient has tried generic dronabinol capsules; OR
Patient cannot swallow or has difficulty swallowing capsules.

Conditions Not Recommended for Approval
Coverage of dronabinol products is not recommended in the following situations:

Chronic Non-Cancer Pain. Based on a review of published studies, there is insufficient evidence for the use of dronabinol in non-cancer pain due to the small study sizes and moderate to high risk of bias to allow for a definitive conclusion.4 In the two studies reviewed, the authors reported mixed effects for pain measures for dronabinol. More data are needed to define the place in therapy of dronabinol in the treatment of chronic non-cancer pain.

Multiple Sclerosis. Results from one published, randomized, double-blind, placebo-controlled study (n = 498) demonstrated that dronabinol has no overall effect on the progression of multiple sclerosis in patients with primary and secondary progressive multiple sclerosis.5 More data are needed to define the place in therapy of dronabinol in the treatment of multiple sclerosis.

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

References
Marinol® capsules [prescribing information]. Parsippany, NJ: ThePharmaNetwork; December 2019.
Syndros® oral solution [prescribing information]. Round Rock, TX: Benuvia Therapeutics; May 2024.
The NCCN Clinical Practice Guidelines in Oncology for Antiemesis (Version 2.2024 – September 27, 2024). © 2024 National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed on November 27, 2024.
Butler M, Krebs E, Sunderlin B, Kane R. Medical cannabis for non-cancer pain: a systematic review. (Prepared by Minnesota Evidence-based Practice Center.) 2016. Available at:

https://www.health.state.mn.us/people/cannabis/docs/intractable/medicalcannabisreport.pdf. Accessed on November 27, 2024.
Zajicek J, Ball S, Wright D, et al. Effect of dronabinol on progression in progressive multiple sclerosis (CUPID): a randomised, placebo-controlled trial. Lancet Neurol. 2013;12(9):857-865.