PRIOR AUTHORIZATION POLICY

POLICY: Dronabinol Prior Authorization Policy
- Marinol® (dronabinol capsules – AbbVie, generic)
- Syndros® (dronabinol oral solution – Insys)

REVIEW DATE: 11/16/2022

OVERVIEW

Dronabinol capsules and Syndros are both 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 guidelines regarding the treatment of emesis (version 2.2022 – March 23, 2022) include various antiemetic regimens depending upon the emetogenic potential of the chemotherapy agent(s) being administered.[4] 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 breakthrough nausea or emesis. Other recommended agents for breakthrough nausea or emesis include serotonin receptor antagonists, olanzapine, lorazepam, haloperidol, metoclopramide, scopolamine, prochlorperazine, promethazine, and dexamethasone.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of dronabinol. 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

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

FDA-Approved Indications

1. **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 criteria (A or B):
   - **A)** Generic dronabinol capsules are requested; OR
   - **B)** If brand Marinol is prescribed, the patient meets BOTH of the following criteria (i and ii):
     - **i.** Patient has tried generic dronabinol capsules; AND
     - **ii.** 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.

2. **Nausea and Vomiting Associated with Cancer Chemotherapy in a Patient who has Failed to Respond Adequately to Conventional Antiemetic Treatments.** Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
   - **A)** Patient has failed to respond adequately to at least two conventional antiemetic treatments; AND
     Note: Examples of conventional antiemetic treatments include selective serotonin receptor antagonists (such as ondansetron, granisetron, Anzemet [dolasetron], Aloxi [palonosetron injection]), Akynzeo (netupitant/palonosetron capsules), Emend (aprepitant capsules), Varubi (rolapitant tablets), metoclopramide, prochlorperazine, dexamethasone.
   - **B)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Generic dronabinol capsules are requested; OR
     - **ii.** If brand Marinol is prescribed, the patient meets BOTH of the following criteria (a and b):
       - **a)** Patient has tried generic dronabinol capsules; AND
       - **b)** 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.

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

FDA-Approved Indications

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

2. **Nausea and Vomiting Associated with Cancer Chemotherapy in a Patient who has Failed to Respond Adequately to Conventional Antiemetic Treatments.** Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
   - **A)** Patient has failed to respond adequately to at least two conventional antiemetic treatments; AND
     Note: Examples of conventional antiemetic treatments include selective serotonin [5-HT_3] receptor antagonists (such as ondansetron, granisetron, Anzemet [dolasetron], Aloxi [palonosetron injection]), Akynzeo (netupitant/palonosetron capsules), Emend (aprepitant capsules), Varubi (rolapitant tablets), metoclopramide, prochlorperazine, dexamethasone.
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried generic dronabinol capsules; OR
     - **ii.** Patient cannot swallow or has difficulty swallowing capsules.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of dronabinol is not recommended in the following situations:

1. **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.[5] 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.

2. **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.[6] There is limited published evidence for the use of dronabinol in spasticity and pain in multiple sclerosis.[7,8] An analysis of three studies in patients with spasticity due to multiple sclerosis found some improvement with dronabinol vs. placebo, but it did not reach statistical significance.[7] A small study (n = 24) in patients with pain due to multiple sclerosis found that dronabinol had a modest analgesic effect, but adverse effects were also more frequent with dronabinol over placebo.[8] A study in patients with multiple sclerosis and central neuropathic pain (n = 240) found no difference between dronabinol and placebo in pain intensity.[9] More data are needed to define the place in therapy of dronabinol in the treatment of multiple sclerosis.

3. **Tourette's Syndrome.** Published studies of dronabinol in patients with Tourette's syndrome are lacking.[10] More data are needed to define the place in therapy of dronabinol in the treatment of Tourette's syndrome.

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

REFERENCES

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9. Schimrigk S, Marziniak M, Neubauer C, et al. Dronabinol is a safe long-term treatment option for neuropathic pain patients. *Eur Neurol*. 2017;78(5-6):320-329.
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