Drug Coverage Policy

Effective Date.....4/1/2025
Coverage Policy Number.....IP0719
Policy Title.....Dronabinol Products

Dronabinol Products

- Marinol® (dronabinol capsules – ThePharmaNetwork, generic)
- Syndros® (dronabinol oral solution – Insys/Benuvia)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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.

Medical Necessity Criteria

I. Marinol is considered medically necessary when the following criteria are met:

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 the following:
   A) Preferred product criteria is met for the product as listed in the below tables

2. **Nausea and Vomiting Associated with Cancer Chemotherapy.** Approve for 1 year if the patient meets **BOTH** of the following (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, olanzapine.
   B) Preferred product criteria is met for the product as listed in the below tables

II. Syndros is considered medically necessary when the following criteria are met:

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 the following:
   A) Preferred product criteria is met for the product as listed in the below tables

2. **Nausea and Vomiting Associated with Cancer Chemotherapy.** Approve for 1 year if the patient meets the following (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, olanzapine.
   B) Preferred product criteria is met for the product as listed in the below tables

Employer Plans:

Product	Criteria
Marinol (dronabinol capsules)	The patient has tried the bioequivalent generic product, **dronabinol capsules**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives]

Product	Criteria
	between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
Syndros (dronabinol oral solution)	Patient meets **ONE** of the following (A or B): A) Patient has tried generic dronabinol capsules; OR B) Documentation that the patient cannot swallow or has difficulty swallowing capsules.

Individual and Family Plans:

Product	Criteria
Marinol (dronabinol capsules)	The patient has tried the bioequivalent generic product, **dronabinol capsules**, AND cannot take 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 would result, per the prescriber, in a significant allergy or serious adverse reaction.
Syndros (dronabinol oral solution)	Patient meets **ONE** of the following (A or B): A) Patient has tried generic dronabinol capsules; OR B) Documentation that the patient cannot swallow or has difficulty swallowing capsules.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.[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.

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.[5] More data are needed to define the place in therapy of dronabinol in the treatment of multiple sclerosis.

References

1. Marinol® capsules [prescribing information]. Parsippany, NJ: ThePharmaNetwork; December 2019.
2. Syndros® oral solution [prescribing information]. Round Rock, TX: Benuvia Therapeutics; May 2024.
3. 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.
4. 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.
5. 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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	4/1/2025

The policy effective date is in force until updated or retired.