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: 03/19/2025

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 NATIONAL FORMULARY COVERAGE:

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. This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, the patient is directed to try generic dronabinol capsules (Step 1) prior to brand Marinol or Syndros (Step 2). If the patient is requesting brand Marinol and meets the standard *Dronabinol Products Prior Authorization* criteria, but has not met the Step Therapy requirement (i.e. has not tried generic dronabinol capsules), an approval for generic dronabinol capsules will be authorized. 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.

I. Dronabinol capsules (Marinol, generic) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 (A or B):
   - **A)** Generic dronabinol capsules are requested; OR
   - **B)** If brand Marinol is being requested, the patient meets BOTH of the following (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.** 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)** Patient meets ONE of the following (i or ii):
     - **i.** Generic dronabinol capsules are requested; OR

ii. If brand Marinol is being requested, the patient meets BOTH of the following (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. Syndros (dronabinol oral solution)
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 (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.** 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) 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 COVERED

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

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

1. **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.[4] 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 March 17, 2025.
4. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Title** was updated to add the word "Products" in line with standard formatting and "with Step Therapy". **Nausea and Vomiting Associated with Cancer Chemotherapy:** Diagnosis was updated to remove "in a Patient who has Failed to Respond Adequately to Conventional Antiemetic Treatments" as this is redundant to the criterion requiring patients to have failed to adequately respond to at least two conventional antiemetic treatments. The criteria note that contains examples of conventional antiemetic treatments was updated to include: olanzapine. **Conditions Not Covered** : Indication of "Tourette's Syndrome" was removed.	11/15/2023
Annual Revision	No criteria changes.	12/11/2024
Early Annual Revision	**Policy Statement** was updated to add "This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, the patient is directed to try generic dronabinol capsules (Step 1) prior to brand Marinol or Syndros (Step 2). If the patient is requesting brand Marinol and meets the standard *Dronabinol Products Prior Authorization* criteria, but has not met the Step Therapy requirement (i.e. has not tried generic), an approval for generic dronabinol capsules will be authorized." Throughout the Policy, the requirement for if Brand name being "prescribed" was reworded to "requested". **Conditions Not Covered** : Indication of "Chronic Non-Cancer Pain" was removed.	03/19/2025