Pharmacy Policy Bulletin: J-0494 Syndros (dronabinol) oral solution – Commercial and Healthcare Reform	
Number: J-0494	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0494-012	**Original Date:** 09/07/2016
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Syndros (dronabinol) oral solution
FDA-Approved Indication(s):	• Treatment of adults with anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS) • Treatment of adults with nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments

Background:	• Syndros is a pharmaceutical version of tetrahydrocannabinol (THC), the active ingredient of cannabis, which activates cannabinoid receptors CB1 and CB2. Most effects, such as appetite enhancement and muscle relaxation, are mediated by central cannabinoid receptors (CB1). • Guidelines from the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) state that dronabinol can be utilized in refractory nausea and vomiting cases and as a rescue antiemetic. 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. Guideline-recommended antiemetic agents include: ○ aprepitant (Emend) ○ dexamethasone (Decadron) ○ dolasetron (Anzemet) ○ dronabinol (Marinol) ○ fosaprepitant (Emend) ○ fosnetupiant-palonosetron (Akynzeo) ○ granisetron (Kytril, Sancuso) ○ haloperidol (Haldol) ○ lorazepam (Ativan) ○ metoclopramide (Reglan) ○ netupitant-palonosetron (Akynzeo) ○ olanzapine (Zyprexa) ○ ondansetron (Zofran)

	○ palonosetron (Aloxi) ○ prochlorperazine (Compazine) ○ promethazine (Phenergan) ○ rolapitant (Varubi) ○ scopolamine (Transderm Scop) • Prescribing Considerations: ○ The member should be under the supervision of an oncologist or infectious disease specialist. ○ Dronabinol oral solution has greater oral bioavailability than dronabinol capsules (2.1 mg oral solution = 2.5 mg capsules). Recommended starting doses are dronabinol oral solution (4.2 mg/m^2) or dronabinol capsules (5 mg/m^2) both given three to four times daily. ○ Syndros is contraindicated in patients with a sensitivity to alcohol and patients receiving, or who have received, disulfiram- or metronidazole-containing products within the past 14 days. Marinol (dronabinol) capsules are contraindicated in patients with a history of hypersensitivity to sesame oil.

Approval Criteria

I. Initial Authorization

A. Appetite Stimulant Therapy
When a benefit, coverage of Syndros may be approved when all of the following criteria are met **(1. through 4.)**:
1. The member is 18 years of age or older.
2. The member has a diagnosis of anorexia associated with weight loss due to AIDS (ICD-10: R64).
3. The prescriber provides documentation of the member's initial weight.
4. The member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred generic dronabinol capsules.

B. Anti-emetic Therapy
When a benefit, coverage of Syndros may be approved when all of the following criteria are met **(1. through 4.)**:
1. The member is 18 years of age or older.
2. The member has a diagnosis of nausea and vomiting (ICD-10: R11), associated with cancer chemotherapy.
3. The member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred generic dronabinol capsules.
4. The member has experienced therapeutic failure, intolerance, or contraindication to two (2) standard of care antiemetic agents per NCCN guidelines.

II. Reauthorization

A. Appetite Stimulant Therapy
When a benefit, reauthorization of Syndros may be approved when the following criterion is met **(1.)**:
1. The prescriber submits documentation of increase in weight from baseline.

B. Anti-Emetic Therapy
When a benefit, reauthorization of Syndros may be approved when the following criterion is met **(1.)**:
1. The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will be approved only if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Syndros [package insert]. Round Rock, TX: Benuvia Operations, LLC; May 2024.
2. Marinol [package insert]. North Chicago, IL: AbbVie Inc.; January 2023.
3. NCCN Guidelines. Antiemesis v.2.2025. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed August 5, 2025.
4. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2020;38(24):2782-2797.