PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**DRONABINOL PRODUCTS**
BRAND NAME* **(generic)**	**MARINOL (dronabinol)**
	SYNDROS (dronabinol oral solution)

Status: CVS Caremark® Criteria
Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Marinol
Marinol is indicated in adults for the treatment of:

- 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.

Syndros
Syndros is indicated in adults for the treatment of:

- 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.

COVERAGE CRITERIA

Nausea and Vomiting Associated with Cancer Chemotherapy
Authorization may be granted when the requested drug is being prescribed for nausea and vomiting associated with cancer chemotherapy when the following criteria is met:

- The patient has failed to respond adequately to a conventional antiemetic treatment [NOTE: Examples of conventional antiemetic treatments include dexamethasone, metoclopramide, olanzapine, prochlorperazine, and 5-HT3 receptor antagonists (e.g., Anzemet [dolasetron], granisetron, ondansetron)]

QUANTITY LIMITS APPLY

Marinol (dronabinol) 120 capsules per 25 days*, 360 capsules per 75 days* or Syndros (dronabinol) oral solution 240 mL per 25 days*, 720 mL per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL (DOA)

- 138-J: DOA: 6 months

REFERENCES

1. Marinol [package insert]. Parsippany, NJ: ThePharmaNetwork LLC; January 2023.
2. Syndros [package insert]. Round Rock, TX: Benuvia Therapeutics LLC; September 2022.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 29, 2023.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/29/2023).
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 30, 2023.
6. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2020; 38:2782-2797.
7. American Society of Clinical Oncology. What is Chemotherapy? https://www.cancer.net/navigating-cancer-care/how-cancer-treated/chemotherapy/what-chemotherapy. May 2022. Accessed November 30, 2023.
8. American Cancer Society. How is Chemotherapy Used to Treat Cancer? https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-is-chemotherapy-used-to-treat-cancer.html. November 2019. Accessed November 30, 2023.