CVS Caremark®

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| Reference number(s) |
| 138-J |

# Post Limit Prior Authorization Dronabinol Dronabinol Products

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Marinol | dronabinol | all |
| Syndros | dronabinol | oral solution |

## Indications

### 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; October 2022.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 29, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/29/2024).
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2024. Available at https://www.nccn.org/professionals/physician\_gls/pdf/antiemesis.pdf. Accessed November 29, 2024.
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 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 27, 2024.