PRIOR AUTHORIZATION CRITERIA

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

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 392-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

FDA-APPROVED INDICATIONS

Marinol and Syndros are indicated 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

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is receiving the requested drug for nausea and vomiting associated with cancer chemotherapy

AND

- The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE of the following antiemetic agents: A) dexamethasone, B) metoclopramide, C) promethazine, D) prochlorperazine, E) olanzapine, F) oral 5-HT3 receptor antagonists (e.g., ondansetron, granisetron, Anzemet [dolasetron])

OR

- The patient has the diagnosis of anorexia associated with weight loss due to Acquired Immune Deficiency Syndrome (AIDS)

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Marinol and Syndros are approved for nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. Marinol and Syndros are also indicated for the treatment of anorexia-associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS).

Per guidelines by the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO), dronabinol is recommended for use when patients experience nausea and vomiting despite optimal prophylaxis with conventional or first-line antiemetic therapies. Therefore, patients must have tried at least one conventional therapy (dexamethasone, metoclopramide, promethazine, prochlorperazine, olanzapine, or oral 5-HT3 receptor antagonists [e.g., ondansetron, granisetron, Anzemet (dolasetron)]).[5,6]

Dronabinol was evaluated in clinical trials in patients with cancer. Dronabinol dosages ranged from 2.5 milligrams (mg) to 40 mg per day, administered in equally divided doses every four to six hours (four times daily). Most patients respond to 5

mg three or four times daily. Doses may be escalated during a chemotherapy cycle or at subsequent cycles, based upon initial results. Therapy should be initiated at the lowest recommended dosage and titrated to clinical response.

Dosing for appetite stimulation should start at 2.5 mg administered twice daily before lunch and supper (once daily if poorly tolerated). Doses may be gradually increased to a maximum of 20 mg per day in divided oral doses if clinically indicated and the patient is not experiencing significant adverse effects.

The limit will accommodate the treatment of Acquired Immune Deficiency Syndrome (AIDS) associated weight loss (20 mg per day in divided doses) as well as chemotherapy-related nausea and vomiting during a chemotherapy cycle up to the maximum dosage of 40 mg per day.

The quantity limit is set at 240 milliliters (mL) of Syndros (dronabinol) oral solution (5 mg/mL) or 120 Marinol (dronabinol) capsules per month to allow for up to a 40 mg dose of dronabinol per day. There will also be a 3-month limit of 720 milliliters (mL) of Syndros (dronabinol) oral solution (5 mg/mL) or 360 Marinol (dronabinol) capsules since dronabinol can be used chronically for AIDS-associated weight loss.

REFERENCES

1. Marinol [package insert]. North Chicago, IL: AbbVie Inc.; August 2017.
2. Syndros [package insert]. Chandler, AZ: Insys Therapeutics, Inc.; May 2017.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January 2018.
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5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. V.2.2017. Available at: www.nccn.org . Accessed January 2018.
6. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Onc* 2017; 35:3240-3261.

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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for nausea and vomiting associated with cancer chemotherapy? [If no, then skip to question 3.]	Yes	No
2	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to at least ONE of the following antiemetic agents: A) dexamethasone, B) metoclopramide, C) promethazine, D) prochlorperazine, E) olanzapine, F) oral 5-HT3 receptor antagonists (e.g., ondansetron, granisetron, Anzemet [dolasetron])? [If yes, then skip to question 4.]	Yes	No
3	Does the patient have a diagnosis of anorexia associated with weight loss due to Acquired Immune Deficiency Syndrome (AIDS)?	Yes	No
4	Does the patient require use of MORE than the plan allowance PER MONTH of 120 capsules of Marinol (dronabinol) or 240 milliliters (mL) of Syndros (dronabinol) oral solution?	Yes	No

[Rph Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.]

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Go to 3	
2.	Go to 4	Deny	Your plan covers this drug when you meet all of these conditions: - You take chemotherapy and have nausea and vomiting - You have tried other drugs and they either did not work for you or you cannot use them Your use of this drug does not meet the requirements. This is based on the information we have.
3.	Go to 4	Deny	Your plan covers this drug when you meet one of these conditions: - You take chemotherapy and have nausea and vomiting - You have anorexia and weight loss due to AIDS (Acquired Immune Deficiency Syndrome). Your use of this drug does not meet the requirement. This is based on the information we have.
4.	Deny Rph Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 6 Months/see Quantity Limit chart	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 120 capsules per month of Marinol (dronabinol) or - 240 milliliters of Syndros (dronabinol) oral solution You have been approved for the maximum quantity that your plan covers for a duration of 6 months. Your request for additional quantities of the requested drug and strength has been denied.

Quantity Limit**		
Drug	**Quantity/25 days***	**Quantity/75 days***
Marinol 2.5 mg, 5 mg, 10 mg capsules	120 capsules	360 capsules
Syndros oral solution	240 mL	720 mL
**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.*		
*** Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.*		