UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cesamet, Marinol, Syndros

Program	Prior Authorization
Medication	Cesamet (nabilone), Marinol (dronabinol), Syndros (dronabinol) oral solution
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Drug Name: Cesamet (nabilone)

Indications

Nausea and Vomiting Associated with Cancer Chemotherapy
Indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. This restriction is required because a substantial proportion of any group of patients treated with Cesamet can be expected to experience disturbing psychotomimetic reactions not observed with other antiemetic agents. Because of its potential to alter the mental state, Cesamet is intended for use under circumstances that permit close supervision of the patient by a responsible individual particularly during initial use of Cesamet and during dose adjustments. Cesamet contains nabilone, which is controlled in Schedule II of the Controlled Substances Act. Schedule II substances have a high potential for abuse. Prescriptions for Cesamet should be limited to the amount necessary for a single cycle of chemotherapy (i.e., a few days). Cesamet capsules are not intended to be used on as needed basis or as a first antiemetic product prescribed for a patient. As with all controlled drugs, prescribers should monitor patients receiving nabilone for signs of excessive use, abuse and misuse. Patients who may be at increased risk for substance abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse) or mental illness.

Drug Name: Marinol (dronabinol), Syndros (dronabinol) oral solution

Indications

Anorexia in patients with AIDS

Indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS

Nausea and Vomiting Associated with Cancer Chemotherapy
Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

2. Coverage Criteria:

A. <u>Chemotherapy-induced nausea and vomiting: Cesamet</u>

1. Patient is receiving cancer chemotherapy

-AND-

2. History of failure, contraindication, or intolerance to formulary generic dronabinol

-AND-

3. History of failure, contraindication, or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

-AND-

4. History of failure, contraindication, or intolerance to one of the following:

    - Ativan (lorazepam)
    - Compazine (prochlorperazine)
    - Decadron (dexamethasone)
    - Haldol (haloperidol)
    - Phenergan (promethazine)
    - Reglan (metoclopramide)
    - Zyprexa (olanzapine)

Authorization will be issued for 12 months.

B. <u>Chemotherapy-induced nausea and vomiting: Syndros</u>

1. Patient is receiving cancer chemotherapy

-AND-

2. **<u>One</u>** of the following:
    a. History of failure, contraindication, or intolerance to formulary generic dronabinol

-OR-

    b. Patient is unable to swallow capsules

-AND-

3. History of failure, contraindication, or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

-AND-

4. History of failure, contraindication, or intolerance to one of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Authorization will be issued for 12 months.

C. <u>Chemotherapy-induced nausea and vomiting: Generic Dronabinol</u>

1. Patient is receiving cancer chemotherapy

-AND-

2. History of failure, contraindication, or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

-AND-

3. History of failure, contraindication, or intolerance to one of the following:

    - Ativan (lorazepam)
    - Compazine (prochlorperazine)
    - Decadron (dexamethasone)
    - Haldol (haloperidol)
    - Phenergan (promethazine)
    - Reglan (metoclopramide)
    - Zyprexa (olanzapine)

Authorization will be issued for 12 months.

D. <u>Anorexia in Patients with AIDS: Syndros</u>

1. Diagnosis of anorexia with weight loss in patients with AIDS

-AND-

2. Patient is on antiretroviral therapy

-AND-

3. One of the following:

    a. Patient is 65 years of age or greater

-OR-

    b. Both of the following:
        - Patient is less than 65 years of age
        - History of failure, contraindication, or intolerance to Megace (megestrol)

-AND-

4. **<u>One</u>** of the following:
    a. History of failure, contraindication, or intolerance to formulary generic dronabinol

-OR-

    b. Patient is unable to swallow capsules

Authorization will be issued for 12 months.

E. Anorexia in Patients with AIDS: Generic dronabinol

1. Diagnosis of anorexia with weight loss in patients with AIDS

-AND-

2. Patient is on antiretroviral therapy

-AND-

3. One of the following:

   a. Patient is 65 years of age or greater

   -OR-

   b. Both of the following:
      - Patient is less than 65 years of age
      - History of failure, contraindication, or intolerance to Megace (megestrol)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Cesamet [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc.; March 2020.
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Antiemesis v.2.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed September 11, 2020.
3. Marinol [package insert]. North Chicago, IL: AbbVie Inc.; December 2018.
4. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed August 22, 2016.

5. The American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2015;63(11):2227-26.
6. Pascual Lopez A, Roque i Figuls M, Urrutia Cuchi G, et al. Systematic review of megestrol acetate in the treatment of anorexia-cachexia syndrome. J Pain Symptom Manage 2004;27:360-369.
7. Per clinical consult with HIV specialist, February 4, 2013.
8. Syndros [package insert]. Chandler, AZ: Insys Therapeutic, Inc.; September 2018.
9. Williams B, Waters D, Parker K. Evaluation and Treatment of Weight Loss in Adults with HIV Disease. Am Fam Physician. 1999;60(3):843-854.
10. Grinspoon S, Mulligan K; Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

Program	Prior Authorization- Cesamet, Marinol, Syndros
Change Control	
Date	Change
March 2013	New policy
June 2014	Annual Review
Dec 2015	▪Updated template to current UHC standard ▪ Revised drug examples list in the Nausea and Vomiting Associated with Cancer Chemotherapy sections for Cesamet and Dronabinol. ▪ Revised criterion requiring trial and failure of Megace. It is a HRM and should be used in patients less than 65 years of age therefore plan will only require trial and failure of Megace if patient is less than 65 years of age. ▪ Updated AIDS wasting criteria to remove nutritional therapy requirement.
October 2016	Updated to align with ORx criteria. Updated policy template.
March 2017	Updated all authorization durations to 12 months. Updated policy template.
October 2018	Renamed Cesamet, Marinol, Syndros. Updated policy to include Syndros. Updated background and references. Revised authorization duration statement to remove reauthorization language.
October 2019	Removed Brand Marinol as requests would be evaluated using Global Non-Preferred criteria. Updated references.
October 2020	Annual review. Added clinical rules section. No updates to clinical criteria. Updated references.