UnitedHealthcare Community Plan

Clinical Pharmacy Program Guideline for Cesasmet and Marinol

Program	Prior Authorization
Medication	Cesamet (nabilone), Marinol (dronabinol)
Pharmacy & Therapeutics Approval Date	11/2016
Effective Date	1/2017

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 (ie, 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)

Indications

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

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

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2. Coverage Criteria:

A. <u>Chemotherapy-induced nausea and vomiting: Cesamet or Brand Marinol</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 [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] [2]

-AND-

4. History of failure, contraindication, or intolerance to one of the following: [2,A]

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

Authorization will be issued for 6 months. Requests for continuation of therapy will be reviewed using the above criteria. Reauthorization may be issued for up to 6 months.

***Haloperidol, lorazepam, metoclopramide and promethazine are recommended only for patients < 65 years old. [B] **This product may require prior authorization.**

B. <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 [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] [2]

-AND-

3. History of failure, contraindication, or intolerance to one of the following: [2,A]

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

Authorization will be issued for 6 months. Requests for continuation of therapy will be reviewed using the above criteria. Reauthorization may be issued for up to 6 months.

***Haloperidol, lorazepam, metoclopramide and promethazine are recommended only for patients < 65 years old. [B]**

C. <u>Anorexia in Patients with AIDS: Brand Marinol</u>

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

-AND-

2. Patient is on antiretroviral therapy [8,C]

-AND-

3. One of the following [B]:

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

Authorization will be issued for 12 months.

***This product may require prior authorization.**

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

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

-AND-

2. Patient is on antiretroviral therapy [8,C]

-AND-

3. One of the following [B]:

c. Patient is 65 years of age or greater

-OR-

d. 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.

4. Endnotes

A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), antispasmodics (scopolamine) and 5-HT3 receptor antagonists (dolasetron, granisetron, ondansetron). [2]
B. These drugs are included either on the 2014 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) or in the American Geriatrics Society 2012 Beers Criteria update. [4-5]
C. Treatment of wasting syndrome includes medical intervention, correction of dental problems and implementation of nutritional support, as well as patient education regarding the importance of exercise and the need to adhere to a highly active antiretroviral regimen. [8]

5. References:

1. Cesamet Prescribing Information. Meda Pharmaceuticals Inc, September 2013.
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Antiemesis v.1.2014. National Comprehensive Cancer Network Web site. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#. Accessed October 3, 2013.
3. Marinol Prescribing Information. Banner Pharmacaps, Inc., February 2013.
4. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed March 12, 2014.
5. The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2012;60(4):616-31.
6. Ockenga J, Grimble R, Jonkers-Schuitema C, et al. ESPEN Guidelines on Enteral Nutrition: Wasting in HIV and other chronic infectious diseases. Clinical Nutrition. 2006:25:319-329.
7. Schtuz T, Herbst B, Koller M. Methodology for the development of the ESPEN Guidelines on Enteral Nutrition. Clinical Nutrition. 2008:25:203-209.
8. 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.
9. 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.
10. Per clinical consult with HIV specialist, February 4, 2013.

Program	Prior Authorization- Cesamet.Marinol
Change Control	
Date	Change
March 2013	New policy
June 2014	Annual Review
Dec 2015	▪Updated template to current UnitedHealthcare 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.