Clinical Pharmacy Program Guideline for Cesamet and Marinol

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tbody>
<tr>
<td>Medication</td>
<td>Cesamet (nabilone), Marinol (dronabinol)</td>
</tr>
<tr>
<td>Pharmacy &amp; Therapeutics Approval Date</td>
<td>11/2016</td>
</tr>
<tr>
<td>Effective Date</td>
<td>1/2017</td>
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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)

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.
2. Coverage Criteria:

A. Chemotherapy-induced nausea and vomiting: Cesamet or Brand Marinol

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. Chemotherapy-induced nausea and vomiting: Generic Dronabinol

1. Patient is receiving cancer chemotherapy
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. **Anorexia in Patients with AIDS: Brand Marinol**

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. 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 [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:

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>March 2013</td>
<td>New policy</td>
</tr>
<tr>
<td>June 2014</td>
<td>Annual Review</td>
</tr>
<tr>
<td>Dec 2015</td>
<td>• Updated template to current UnitedHealthcare standard</td>
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<tr>
<td></td>
<td>• Revised drug examples list in the Nausea and Vomiting Associated</td>
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<td></td>
<td>with Cancer Chemotherapy sections for Cesamet and Dronabinol.</td>
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<td></td>
<td>• Revised criterion requiring trial and failure of Megace. It is a HRM</td>
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<tr>
<td></td>
<td>and should be used in patients less than 65 years of age therefore</td>
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<tr>
<td></td>
<td>plan will only require trial and failure of Megace if patient is</td>
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<td></td>
<td>less than 65 years of age.</td>
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<tr>
<td></td>
<td>• Updated AIDS wasting criteria to remove nutritional therapy</td>
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<td></td>
<td>requirement.</td>
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<tr>
<td>October 2016</td>
<td>Updated to align with ORx criteria. Updated policy template.</td>
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