Cannabinoids

Description

Cesamet (nabilone), Marinol (dronabinol) capsules, Syndros (dronabinol) oral solution

Background

Cesamet (nabilone), Marinol (dronabinol capsules) and Syndros (dronabinol oral solution) are orally active synthetic cannabinoids which have complicated effects on the central nervous system (CNS) and interact with various receptors in different regions of the brain. There are two cannabinoid receptors that have been found in the brain, CB1 and CB2. Cannabinoids bind to these receptors and act as agonists. However, the mechanism of action is still somewhat unknown, when CB1 receptors are blocked (antagonized, opposite action of cannabinoids), nausea and vomiting are induced. Therefore, since these agents are agonists to that receptor, cannabinoids are thought to improve nausea and vomiting in this way (1).

Dronabinol containing products can also exhibit appetite stimulating effects which can be used to treat anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). These effects are mediated CB receptors in the lateral hypothalamus. Tachyphylaxis and tolerance develop to some of the cardiovascular and CNS effects, however, this tolerance does not appear to develop to the appetite stimulant effect of dronabinol (3-4).

Regulatory Status

FDA approved indications (2-4):
1. Cesamet (nabilone) is 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. Marinol (dronabinol) capsules are indicated in adults for the following:
   a. The treatment of anorexia associated with weight loss in patients with AIDS
   b. The treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

3. Syndros (dronabinol) is indicated in adults for the following:
   a. The treatment of anorexia associated with weight loss in patients with AIDS
   b. The treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Before use of these agents, prescribers should assess risk for abuse or misuse in patients with a history of substance abuse or dependence, and monitor for the development of associated behaviors or conditions throughout therapy. These agents may cause psychiatric and cognitive effects and impair mental and/or physical abilities. Avoid use in patients with a psychiatric history. Monitor for symptoms and avoid concomitant use of drugs with similar effects (2-4).

The safety and effectiveness of Cesamet, Marinol, and Syndros in pediatric patients have not been established (2-4).

**Related policies**
5HT-3 Antagonists, NK-1 Antagonists

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cesamet, Marinol, and Syndros may be considered **medically necessary** for patients 18 years and older for the treatment of nausea and vomiting associated with cancer chemotherapy or of anorexia associated with weight loss in patients with AIDS and if the conditions indicated below are met.
Marinol, and Syndros may be considered medically necessary for patients 18 years and older for the treatment of anorexia associated with weight loss in patients with AIDS and if the conditions indicated below are met.

Cesamet, Marinol, and Syndros may be considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements
Prior authorization is not required if prescribed by an oncologist and/or the member has paid pharmacy claims for an oncology medication(s) in the past 6 months

Age 18 years of age and older

Diagnoses

Patient must have ONE of the following:

Cesamet, Marinol and Syndros

1. Nausea and vomiting associated with cancer chemotherapy

Marinol and Syndros only

1. Anorexia associated with weight loss in patients with AIDS

Prior–Approval Renewal Requirements

Age 18 years of age and older

Diagnoses

Patient must have ONE of the following:

Cesamet, Marinol and Syndros
1. Nausea and vomiting associated with cancer chemotherapy

**Marinol and Syndros only**
1. Anorexia associated with weight loss in patients with AIDS

### Policy Guidelines

#### Pre–PA Allowance

**Quantity**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Strength</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Cesamet</td>
<td>1 mg</td>
<td>18 capsules per 90 days</td>
</tr>
<tr>
<td>Marinol</td>
<td>2.5 mg, 5 mg, 10 mg</td>
<td>180 capsules per 90 days</td>
</tr>
<tr>
<td>Syndros oral solution</td>
<td>5 mg/mL</td>
<td>360 mLs per 90 days</td>
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</tbody>
</table>

#### Prior–Approval Limits

**Quantity**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Strength</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesamet</td>
<td>1 mg</td>
<td>180 capsules per 90 days OR</td>
</tr>
<tr>
<td>Marinol</td>
<td>2.5 mg, 5 mg, 10 mg</td>
<td>360 capsules per 90 days OR</td>
</tr>
<tr>
<td>Syndros oral solution</td>
<td>5 mg/mL</td>
<td>720 mLs per 90 days</td>
</tr>
</tbody>
</table>

**Duration** 12 months

#### Prior–Approval *Renewal* Limits

Same as above

### Rationale
Summary
Cesamet, Marinol, and Syndros are orally active synthetic cannabinoid which are thought to have their therapeutic effect through CB1 receptors. These agents are agonists to that receptor and are thought to improve nausea and vomiting in this way. Dronabinol containing products can also stimulate appetite which can be used to treat anorexia associated with weight loss in patients with AIDS (1-4).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Cesamet, Marinol, and Syndros while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>June 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review and reference update</td>
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<tr>
<td>March 2019</td>
<td>Annual review</td>
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</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.