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5.50.017

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	June 15, 2018
Subject:	Cannabinoids	**Page:**	1 of 5

Last Review Date: March 8, 2024

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, Barhemsys, 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** if the conditions indicated below are met.

Cesamet, Marinol, and Syndros may be considered **investigational** 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

Medication	Strength	Quantity Limit
Cesamet	1 mg	18 capsules per 90 days
Marinol	2.5 mg, 5 mg, 10 mg	180 capsules per 90 days
Syndros oral solution	5 mg/mL	360 mL per 90 days

Prior–Approval Limits

Quantity

Medication	Strength	Quantity Limit
Cesamet	1 mg	180 capsules per 90 days **OR**
Marinol	2.5 mg, 5 mg, 10 mg	360 capsules per 90 days **OR**
Syndros oral solution	5 mg/mL	720 mL per 90 days

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

1. Smith LA, Azariah F, Lavender VT, Stoner NS, Bettiol S. Cannabinoids for nausea and vomiting in adults with cancer receiving chemotherapy. Cochrane Database Syst Rev. 2015;(11):CD009464.
2. Cesamet [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; February 2021.
3. Marinol [package insert]. North Chicago, IL: AbbVie, Inc.; August 2017.
4. Syndros [package insert]. Chandler, AZ: Benuvia Therapeutics, Inc.; September 2018.

Policy History

Date	Action
June 2018	Addition to PA
September 2018	Annual review and reference update
March 2019	Annual review
March 2020	Annual review
March 2021	Annual editorial review and reference update
June 2021	Annual review
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.50.017
June 2023	Annual review
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.