Clinical Policy: Nabilone (Cesamet)

Reference Number: ERX.NPA.35
Effective Date: 09.01.17
Last Review Date: 08.17

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Nabilone (Cesamet®) is a synthetic cannabinoid. It has been suggested that the anti-emetic effect of nabilone is caused by interaction with the cannabinoid receptor system, i.e., the CB1 receptor, which has been discovered in neural tissues.

FDA approved indication
Cesamet is 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.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Cesamet is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chemotherapy Induced Nausea and Vomiting (must meet all)**:**

1. Requested therapy will be used for treatment or prophylaxis of nausea/vomiting due to chemotherapy;
2. Age ≥ 18 years;
3. Failure of oral ondansetron and generic Kytril (granisetron), unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of dronabinol, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 6 mg/day (6 tablets/day).

Approval duration: Duration of chemotherapy

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chemotherapy Induced Nausea and Vomiting (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 6 mg/day (6 tablets/day).

Approval duration: Duration of chemotherapy

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Zofran® (ondansetron)	24 mg PO 30 minutes prior to chemotherapy OR 8 mg PO 30 minutes prior to chemotherapy and repeat in 8 hours, then 8 mg every 12 hours for 1 to 2 days post-chemotherapy	24 mg/day
Kytril® (granisetron)	2 mg PO 1 hour before chemotherapy OR 1 mg PO 1 hour before and 1 mg 12 hours after chemotherapy	2 mg/day
Marinol® (dronabinol)	Capsules: 5 mg/m^2 PO 1 to 3 hours prior to chemotherapy, then 5 mg/m^2 every 2 to 4 hours after chemotherapy for a total of 4 to 6 doses/day Solution: 4.2 mg/m^2 rounded to the nearest 0.1 increment PO 1 to 3 hours prior to chemotherapy, then 4.2 mg/m^2 every 2 to 4 hours after chemotherapy for a total of 4 to 6 doses/day	Capsules: 15 mg/m^2/dose Solution: 12.6 mg/m^2/dose for 4 to 6 doses/day

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Chemotherapy induced nausea and vomiting	1 or 2 mg PO BID. On the day of chemotherapy, the initial dose should be given 1 to 3 hours before the chemotherapeutic agent is administered. To minimize side effects, it is recommended that the lower starting dose be used and that the dose be increased as necessary. A dose of 1 or 2 mg the night before may be useful. Cesamet may be administered 2 or 3 times a day during the entire course of each cycle of chemotherapy and, if needed, for 48 hours after the last dose of each cycle of chemotherapy.	6 mg/day

VI. Product Availability

Capsules: 1 mg

VII. References

1. Cesamet Prescribing Information. Quebec, Canada: Valeant Pharmaceuticals North America LLC; September 2013. Available at: www.cesamet.com. Accessed July 17, 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com/.

3. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 17, 2017.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 17, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
- Policy split from ERX.NSMN.18 Anti-emetics and converted to new template. - Removed coverage of Cesamet for radiation-induced nausea/vomiting as this is not an FDA-approved indication, nor is its use for this indication supported by compendia. - Added age limit.	07.17.17	08.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.