

## **Clinical Policy: Dronabinol (Marinol, Syndros)**

Reference Number: CP.PMN.159

Effective Date: 11.16.16

Last Review Date: 08.23

Line of Business: Commercial, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Dronabinol (Marinol<sup>®</sup>, Syndros<sup>®</sup>) is a cannabinoid.

### **FDA Approved Indication(s)**

Marinol and Syndros are indicated in adults for the treatment of:

- Anorexia associated with weight loss in patients with acquired immune deficiency syndrome (AIDS)
- 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Marinol and Syndros are **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Anorexia Associated with AIDS or Cancer (must meet all):**

1. Diagnosis of anorexia with weight loss in patients with AIDS or cancer;
2. Age  $\geq$  18 years;
3. For age < 65 years, one of the following (a or b):
  - a. Failure of megestrol at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
4. Member must use generic dronabinol capsule, unless one of the following (a or b):
  - a. Generic dronabinol capsule is contraindicated, or clinically significant adverse effects are experienced;
  - b. Request is for Syndros and member is unable to swallow capsules;
5. Dose does not exceed one of the following (a or b):
  - a. Marinol: 20 mg (2 capsules) per day;
  - b. Syndros: 16.8 mg per day.

**Approval duration: 6 months**

##### **B. Nausea and Vomiting Associated with Cancer Chemotherapy (must meet all):**

1. Prescribed for the treatment of chemotherapy-induced nausea/vomiting;

2. Age  $\geq$  18 years;
3. Member is currently receiving cancer chemotherapy (*see Appendix D*);
4. Member meets one of the following (a or b):
  - a. Both of the following (i and ii):
    - i. Failure of a serotonin (5-HT<sub>3</sub>) antagonist (*ondansetron is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
    - ii. Failure of two of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated: metoclopramide, prochlorperazine, lorazepam;
  - b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
5. Member must use generic dronabinol capsule, unless one of the following (a or b):
  - a. Generic dronabinol capsule is contraindicated, or clinically significant adverse effects are experienced;
  - b. Request is for Syndros and member is unable to swallow capsules;
6. Dose does not exceed one of the following (a or b):
  - a. Marinol: 15 mg/m<sup>2</sup> per dose (up to 6 doses per day);
  - b. Syndros: 12.6 mg/m<sup>2</sup> per dose (up to 6 doses per day).

**Approval duration: Projected course of chemotherapy up to 72 hours after completion of chemotherapy**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;

3. For nausea and vomiting treatment requests, member continues to receive cancer chemotherapy;
4. Member must use generic dronabinol capsule, unless one of the following (a or b):
  - a. Generic dronabinol capsule is contraindicated, or clinically significant adverse effects are experienced;
  - b. Request is for Syndros and member is unable to swallow capsules;
5. If request is for a dose increase, new dose does not exceed one of the following (a or b):
  - a. Anorexia associated with AIDS or cancer (i or ii):
    - i. Marinol: 20 mg (2 capsules) per day;
    - ii. Syndros: 16.8 mg per day;
  - b. Treatment of nausea and vomiting associated with cancer chemotherapy (i or ii):
    - i. Marinol: 15 mg/m<sup>2</sup> per dose (up to 6 doses per day);
    - ii. Syndros: 12.6 mg/m<sup>2</sup> per dose (up to 6 doses per day).

**Approval duration:**

**Anorexia associated with AIDS or cancer:** 12 months

**Chemotherapy-induced nausea and vomiting:** Projected course of chemotherapy up to 72 hours after completion of chemotherapy

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

**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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

5-HT<sub>3</sub>: serotonin 5-hydroxytryptamine,  
type 3

AIDS: acquired immune deficiency  
syndrome

ASCO: American Society of Clinical  
Oncology

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer  
Network

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| <b>Drug Name</b>   | <b>Dosing Regimen</b>   | <b>Dose Limit/<br/>Maximum Dose</b>         |
|--|---|---|
| megestrol<br>(Megace <sup>®</sup> )                      | <b>Anorexia Associated with AIDS</b><br>400 to 800 mg PO QD<br><b>Anorexia Associated with Cancer*</b><br>160 to 800 mg PO QD   | 800 mg/day                                  |
| <b>5-HT<sub>3</sub> Serotonin Antagonists</b>            |   |   |
| Akynzeo <sup>®</sup><br>(fosnetupitant/<br>palonosetron) | <b>Prevention of nausea and vomiting associated with highly emetogenic chemotherapy</b><br>1 vial IV given 30 min prior to chemotherapy on day 1  | 1 vial/<br>chemotherapy<br>cycle            |
| Akynzeo <sup>®</sup><br>(netupitant/<br>palonosetron)    | <b>Prevention of nausea and vomiting associated with highly emetogenic chemotherapy</b><br>1 capsule PO given 1 hour prior to initiation of chemotherapy on day 1 (in combination with dexamethasone) or 1 vial IV given 30 min prior to initiation of chemotherapy on day 1  | 1 capsule or vial/<br>chemotherapy<br>cycle |
| Aloxi <sup>®</sup><br>(palonosetron)                     | <b>Prevention of nausea and vomiting associated with chemotherapy</b><br>0.25 mg IV given 30 min prior to chemotherapy  | 0.25 mg/day                                 |
| Anzemet <sup>®</sup><br>(dolasetron)                     | <b>Prevention of nausea and vomiting associated with chemotherapy</b><br>100 mg PO within 1 hr prior to chemotherapy  | 100 mg/day                                  |
| granisetron<br>(Kytril <sup>®</sup> )                    | <b>Prevention of nausea and vomiting associated with chemotherapy</b><br>Tablet: 2 mg PO QD given 1 hr prior to chemotherapy, or 1 mg PO BID (one dose given 1 hr prior to chemotherapy and then 12 hours later)<br><br>Injection: 10 mcg/kg IV given within 30 min prior to chemotherapy (on days chemotherapy is given)<br><br><b>Treatment of nausea and vomiting associated with chemotherapy*</b><br>1 to 2 mg PO daily or 1 mg PO BID or 0.01 mg/kg (maximum 1 mg) IV daily | PO: 2 mg/day<br>IV: 10<br>mcg/kg/day        |

| Drug Name  | Dosing Regimen   | Dose Limit/<br>Maximum Dose                            |
|--|--|--|
| ondansetron<br>(Zofran <sup>®</sup> , Zofran <sup>®</sup><br>ODT, Zuplenz <sup>®</sup> ) | <p><b>Prevention of nausea and vomiting associated with moderately emetogenic chemotherapy</b><br/> <u>Age 12 years or older:</u> 8 mg PO given 30 min prior to chemotherapy, then repeat dose 8 hrs after initial dose, then 8 mg PO BID for 1 to 2 days after chemotherapy completion<br/> <u>Age 4 to 11 years:</u> 4 mg PO given 30 min prior to chemotherapy, then repeat dose 4 and 8 hrs after initial dose, then 8 mg PO TID for 1 to 2 days after chemotherapy completion</p> <p><b>Prevention of nausea and vomiting associated with highly emetogenic chemotherapy</b><br/>           24 mg PO given 30 min prior to start of single-day chemotherapy</p> | PO: 24 mg/day<br>IV: 16 mg/dose<br>(up to 3 doses/day) |
| <b>Miscellaneous Antiemetics</b>   |  |  |
| metoclopramide<br>(Reglan <sup>®</sup> ,<br>Metozolv <sup>®</sup> )                      | <p><b>Prevention of nausea and vomiting associated with chemotherapy</b><br/>           1 to 2 mg/kg/dose IV given 30 min prior to chemotherapy. May repeat every 2 hours for 2 doses, then every 3 hours for 3 doses</p> <p>20 to 40 mg (or 0.5 mg/kg/dose) PO 2 to 4 times daily in combination with dexamethasone*</p>  | 2 mg/kg/dose<br>(up to 3 doses per day)                |
| lorazepam<br>(Ativan <sup>®</sup> )  | <p><b>Prevention of nausea and vomiting associated with chemotherapy*</b><br/>           0.5 to 2 mg PO, IV, or SL Q6 hrs PRN (in combination with other agents)</p>   | 10 mg/day  |
| prochlorperazine<br>(Compazine <sup>®</sup> )  | <p><b>Prevention of nausea and vomiting associated with chemotherapy*</b><br/>           10 mg PO/IV once prior to chemotherapy</p> <p><b>Treatment of nausea and vomiting</b><br/>           5 to 10 mg PO 3 to 4 times per day or 25 mg PR BID</p>   | Prevention: 10 mg/day<br><br>Treatment: 40 mg/day      |

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

\*Off-label

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Marinol: history of a hypersensitivity reaction to dronabinol or sesame oil
  - Syndros:
    - History of hypersensitivity reaction to dronabinol or alcohol

- Due to risk of disulfiram-like reaction, disulfiram- or metronidazole-containing products should be discontinued 14 days prior to initiating Syndros and should not be administered within 7 days of completing treatment with Syndros.
- Boxed warning(s): none reported

*Appendix D: American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) Recommendations in Oncology*

- Minimal emetic risk chemotherapy: No routine prophylaxis is recommended.
- Low emetic risk chemotherapy: Recommended options include dexamethasone (recommended by both ASCO and NCCN) or metoclopramide, prochlorperazine, or a 5-HT<sub>3</sub> receptor antagonist (recommended by NCCN only). NK<sub>1</sub> receptor antagonists are not included in low risk antiemetic recommendations.
- Moderate emetic risk chemotherapy: 5-HT<sub>3</sub> receptor antagonists and dexamethasone may be used in combination and with or without NK<sub>1</sub> receptor antagonists. Olanzapine may also be used in combination with palonosetron and dexamethasone.
  - Examples of moderate emetic risk chemotherapy: 6zacytidine, bendamustine, carboplatin, clofarabine, cyclophosphamide ≤ 1,500 mg/m<sup>2</sup>, cytarabine > 200 mg/m<sup>2</sup>, daunorubicin, doxorubicin < 60 mg/m<sup>2</sup>, epirubicin ≤ 90 mg/m<sup>2</sup>, idarubicin, ifosfamide, irinotecan, oxaliplatin
- High emetic risk chemotherapy: NK<sub>1</sub> receptor antagonists are recommended for use in combination with 5-HT<sub>3</sub> receptor antagonists and dexamethasone. Olanzapine may also be used in combination with 5-HT<sub>3</sub> receptor antagonists, dexamethasone, and/or NK<sub>1</sub> receptor antagonists.
  - Examples of high emetic risk chemotherapy: carmustine, cisplatin, cyclophosphamide > 1,500 mg/m<sup>2</sup>, dacarbazine, mechlorethamine, streptozocin
- Breakthrough emesis: Per NCCN, an agent from a different drug class is recommended to be added to the current antiemetic regimen. Drug classes include atypical antipsychotics (olanzapine), benzodiazepines (lorazepam), cannabinoids (dronabinol, nabilone), phenothiazines (prochlorperazine, promethazine), 5-HT<sub>3</sub> receptor antagonists (dolasetron, ondansetron, granisetron), steroids (dexamethasone), or haloperidol, metoclopramide, scopolamine. An NK<sub>1</sub> receptor antagonist may be added to the prophylaxis regimen of the next chemotherapy cycle if not previously included.

*Appendix E: States with Regulations against Redirections in Stage IV or Metastatic Cancer*

| State | Step Therapy Prohibited? | Notes   |
|-------|--------------------------|---|
| FL    | Yes                      | For stage 4 metastatic cancer and associated conditions.  |
| GA    | Yes                      | For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.   |
| IA    | Yes                      | For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.   |
| LA    | Yes                      | For stage 4 advanced, metastatic cancer or associated conditions. Exception if “clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy. |

| State | Step Therapy Prohibited? | Notes  |
|-------|--------------------------|--|
| NV    | Yes                      | Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person |
| OH    | Yes                      | <i>*Applies to Commercial and HIM requests only*</i><br>For stage 4 metastatic cancer and associated conditions              |
| OK    | Yes                      | <i>*Applies to HIM requests only*</i><br>For advanced metastatic cancer and associated conditions                            |
| PA    | Yes                      | For stage 4 advanced, metastatic cancer  |
| TN    | Yes                      | For advanced metastatic cancer and associated conditions   |
| TX    | Yes                      | For stage 4 advanced, metastatic cancer and associated conditions  |

### V. Dosage and Administration

| Drug Name            | Indication  | Dosing Regimen   | Maximum Dose  |
|----------------------|---|--|---|
| Dronabinol (Marinol) | Anorexia associated with AIDS or cancer               | 2.5 mg PO BID, may titrate up to 10 mg PO BID  | 20 mg/day   |
|                      | Treatment of chemotherapy-induced nausea and vomiting | 5 mg/m <sup>2</sup> PO given 1 to 3 hours prior to chemotherapy, then every 2 to 4 hrs after chemotherapy (total 4 to 6 doses per day).<br><br>May titrate up to 15 mg/m <sup>2</sup> per dose for 4 to 6 doses per day.   | 15 mg/m <sup>2</sup> per dose (max 6 doses per day)   |
| Dronabinol (Syndros) | Anorexia associated with AIDS or cancer               | 2.1 mg PO BID, may titrate up to 8.4 mg PO BID   | 16.8 mg/day   |
|                      | Treatment of chemotherapy-induced nausea and vomiting | 4.2 mg/m <sup>2</sup> PO given 1 to 3 hrs prior to chemotherapy, then every 2 to 4 hrs after chemotherapy (total 4 to 6 doses per day).<br><br>May titrate up to 12.6 mg/m <sup>2</sup> per dose for 4 to 6 doses per day. | 12.6 mg/m <sup>2</sup> per dose (max 6 doses per day) |

### VI. Product Availability

| Drug Name            | Availability                          |
|----------------------|---------------------------------------|
| Dronabinol (Marinol) | Capsules: 2.5 mg, 5 mg, 10 mg         |
| Dronabinol (Syndros) | Oral solution: 5 mg/mL (30 mL bottle) |

### VII. References

1. Marinol Prescribing Information. North Chicago, IL: AbbVie, Inc; January 2023. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/018651s0331bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/018651s0331bl.pdf). Accessed April 19, 2023.

2. Syndros Prescribing Information. Lakewood, NJ: Insys Therapeutics, Inc.; September 2022. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/205525s011lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205525s011lbl.pdf). Accessed April 19, 2023.
3. Hesketh, PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Guideline Update. *J Clin Oncol*. 2020. 38:2,782-2,797. doi.org/10.1200/JCO.20.01296.
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5. National Comprehensive Cancer Network. Palliative Care Version 2.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/palliative.pdf](https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf). Accessed October 10, 2022.
6. 2019 American Geriatric Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc* 00:1-21; DOI: 10.1111/jgs.15767.

| Reviews, Revisions, and Approvals   | Date     | P&T Approval Date |
|---|----------|-------------------|
| 1Q 2019 annual review: no significant changes; references reviewed and updated.   | 10.30.18 | 02.19             |
| 1Q 2020 annual review: no significant changes; references reviewed and updated.   | 11.01.19 | 02.20             |
| 1Q 2021 annual review: no significant changes; references reviewed and updated.   | 11.12.20 | 02.21             |
| Added allowance for bypassing redirection if state regulations do not allow step therapy in Stage IV or metastatic cancer settings with additional details in appendix E.   | 04.27.21 |                   |
| Added Nevada to Appendix E.   | 08.03.21 |                   |
| 1Q 2022 annual review: no significant changes; references reviewed and updated.   | 10.04.21 | 02.22             |
| Template changes applied to other diagnoses/indications and continued therapy section.  | 10.04.22 |                   |
| 1Q 2023 annual review: added requirement that member must use generic dronabinol capsule, unless contraindicated, clinically significant adverse effects or experienced, or member is unable to swallow capsules; modified to generalize beyond Stage IV or metastatic cancer to the following redirection bypass: “Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings”; references reviewed and updated. | 10.10.22 | 02.23             |
| 3Q 2023 annual review: clarified generic redirection bypass if member is unable to swallow capsules applies to Syndros requests only; references reviewed and updated; updated Appendix E to include Oklahoma.  | 04.19.23 | 08.23             |

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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