Syndros™ (dronabinol)

Policy # 00599
Original Effective Date: 01/17/2018
Current Effective Date: 01/08/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Syndros™‡ (dronabinol) to be **eligible for coverage**** when the patient selection criterion is met**.**

Patient Selection Criteria

Coverage eligibility for Syndros (dronabinol) will be considered when the following criteria are met:

- The patient has a diagnosis of Acquired Immunodeficiency Syndrome (AIDS); AND
    - The medication is being used to treat anorexia associated with weight loss; AND
    - The patient is unable to swallow generic dronabinol capsules; AND
    - The patient is not currently taking medications in a tablet and/or capsule form; OR
- The patient has a diagnosis of nausea and vomiting associated with cancer chemotherapy; AND
    - The patient has failed to respond adequately to conventional antiemetic agents; AND
    - The patient is unable to swallow generic dronabinol capsules; AND
    - The patient is not currently taking medications in tablet and/or capsule form.

*(Note: the criterion that requires the patient to be unable to swallow capsules as well as the criterion requiring that patients are not currently taking medications in a tablet or capsule form are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Syndros (dronabinol) when the patient is able to swallow generic dronabinol capsules or is currently taking other medications in tablet or capsule form to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Syndros (dronabinol) for any indication other than anorexia and weight loss associated with AIDS or chemotherapy-induced nausea and vomiting with inadequate response to conventional antiemetic treatments to be **investigational.***

Background/Overview

Syndros is the liquid formulation of dronabinol, which is also available as a generic capsule. All formulations are indicated for the treatment of anorexia associated with weight loss in patients with AIDS and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. As an orally active cannabinoid, dronabinol is known to have complex effects on the central nervous system (CNS) including reversible effects on appetite, mood, cognition, memory, and perception. Dosing for patients with AIDS and anorexia-associated weight loss begins at 2.1 mg twice daily (1 hour before lunch and 1 hour before dinner) and can be increased gradually to 2.1 mg one hour before lunch and 4.2 mg one hour before dinner. The maximum dosage for this indication is 8.4 mg twice daily. The recommended starting dose for patients with chemotherapy-induced nausea and vomiting is 4.2 mg/m^2 administered 1 to 3 hours prior to chemotherapy and then every 2 to 4 hours after chemotherapy for a total of 4-6 doses per day. The maximum dosage for this indication is 12.6 mg/m^2 for each of the 4 to 6 doses per day. Of note, dronabinol is a schedule II controlled substance.

Anorexia and tissue wasting can occur in the later stages of HIV infection, but these symptoms can be reversed if the infection is treated with anti-retroviral therapy (ART). For patients who cannot be treated with ART, either megestrol acetate or a dronabinol product may be useful to stimulate

appetite and weight gain. However, there is limited evidence that either therapy will provide long-term benefit to the patient.

Prevention of chemotherapy-induced nausea and vomiting depends on the emetogenicity of the chemotherapy regimen as well as the type of cancer being treated. Most anti-emetic regimens involve a glucocorticoid combined with a 5-HT3 inhibitor and may include a neurokinin-1 receptor antagonist and olanzapine. Guidelines from the National Comprehensive Cancer Network (NCCN) as well as guidelines from the American Society of Clinical Oncology state that cannabinoids (such as dronabinol) can be considered for refractory nausea and vomiting and as a rescue antiemetic if needed.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Syndros is indicated for the treatment of anorexia associated with weight loss in patients with AIDS and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Rationale/Source

Syndros was approved by the FDA based on studies of dronabinol capsules in patients with AIDS associated anorexia and weight loss and chemotherapy associated nausea and vomiting. The patient selection criteria presented in this policy takes into consideration whether or not the patient can tolerate the generic capsule formulation of dronabinol. Based on a review of the data, if the above mentioned criteria are not met there is no advantage to the use of Syndros over the standard of therapy or the generic oral dronabinol capsules.

References

1. Syndros [package insert]. InsysTherapeutics. Chandler, AZ. May 2017.
2. National comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology. https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf
3. Hesketh PJ, Kris MG, Basch E, Bohlke K, Barbour SY, Clark-Snow RA, Danso MA, Dennis K, Dupuis LL, Dusetzina SB, Eng C, Feyer PC, Jordan K, Noonan K, Sparacio D, Somerfield MR,

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Lyman GH. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2017;35(28):3240-3261.

Policy History

Original Effective Date: 01/17/2018
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01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. New policy.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2020	Medical Policy Committee review
01/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.