BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**7/20/17**
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SYNDROS™ (dronabinol) oral solution

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SYNDROS™ (dronabinol) oral solution (cont.)

Criteria:

- **Criteria for initial therapy:** Syndros (dronabinol) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual is 18 years of age or older

2. A confirmed diagnosis of **ONE** of the following:

   - Anorexia associated with weight loss in an individual with Acquired Immune Deficiency Syndrome (documentation of weight loss is required) in an individual who is receiving highly active antiretroviral therapy (HAART)

   - Nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments

3. **ALL** of the following baseline tests have been completed before initiation of treatment:
   - Psychiatric screening for mania, depression, or schizophrenia

4. Individual has failure, contraindication or intolerance such that the individual is unable to use **ALL** of the following:
   - **For anorexia with weight loss due to AIDS:**
     - Megestrol acetate
     - Marinol (dronabinol) or generic dronabinol cap
   - **For nausea and vomiting associated with cancer chemotherapy:**
     - Cannabinoid:
       - Cesamet (nabilone) cap
       - Marinol (dronabinol) or generic dronabinol cap
     - Combination of serotonin type 3 receptor antagonist plus substance P/neurokinin 1 receptor antagonist plus dexamethasone

5. There are **NO** contraindications:
   - Contraindications include:
     - History of hypersensitivity reaction to dronabinol
     - History of hypersensitivity reaction to alcohol
     - Receiving or have received disulfiram or metronidazole products within the past 14 days

6. Will not be used in a woman who is pregnant or likely to become pregnant

7. Will not be used in a woman who is breast feeding an infant or child

8. Will not be used with metronidazole or disulfiram 14 days prior to and 7 days after stopping Syndros

Initial approval duration: 12 months

SYNDROS™ (dronabinol) oral solution (cont.)

- **Criteria for continuation of coverage (renewal request):** Syndros (dronabinol) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
    - Anorexia associated with weight loss in AIDS syndrome response is defined as **BOTH** of the following:
        - Achieved and maintains at least a 10% increase in weight **or** has not demonstrated further weight loss
        - Continues to receive highly active antiretroviral therapy
    - Nausea and vomiting associated with cancer chemotherapy response is defined as **BOTH** of the following:
        - Achieved and maintains at least a 30% improvement in the frequency of nausea and vomiting from cancer chemotherapy (complete or partial response)
        - Continues to receive cancer chemotherapy
2. Individual has been adherent with the medication
3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section
    - Significant adverse effect such as:
        - Seizure that occurs while on Syndros
        - Worsening nausea, vomiting, or abdominal pain while on Syndros
4. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Syndros (dronabinol) oral solution is a cannabinoid indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS); and it is indicated for nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. Syndros (dronabinol) oral solution contains 50% (w/w) dehydrated alcohol and 5.5% (w/w) propylene glycol. It is classified as Schedule II of the Controlled Substances Act.

Dronabinol is synthetic delta-9-tetrahydrocannabinol (delta-9-THC). Delta-9-tetrahydrocannabinol is also a naturally occurring component of *Cannabis sativa L.* (marijuana). Dronabinol has complex effects on the central nervous system, including central sympathomimetic activity. Cannabinoid receptors have been discovered in neural tissues. These receptors may play a role in mediating the effects of dronabinol and other cannabinoids.

Recommendations on treatment of nausea and vomiting due to cancer chemotherapy organize use of medications for nausea and vomiting by the degree of risk for the development of nausea and vomiting from the cancer chemotherapy regimen. For low emetic risk, dexamethasone, metoclopramide, prochlorperazine, or serotonin type 3 receptor antagonists should be used. For moderate emetic risk, a two-drug regimen of

SYNDROS™ (dronabinol) oral solution (cont.)

dexamethasone plus serotonin type 3 receptor antagonists are recommended. A three-drug regimen of dexamethasone plus serotonin type 3 receptor antagonists plus a substance P/neurokinin is recommended for high emetic risk cancer chemotherapy.

Anorexia, cachexia, and chronic nausea occur frequently in HIV infection. Various treatment options exist for HIV wasting syndrome and include appetite stimulants (megestrol acetate, dronabinol, and mirtazapine) and anabolic agents (testosterone, testosterone analogs). The decision of which agent(s) to choose should include comorbidities, drug–drug interactions, past medical history, and the ability to use and tolerate certain formulations.

Definitions:

Anti-emetic agents:

Serotonin type 3 receptor antagonist:
- Anzemet (dolasetron) tab
- Granisetron tab
- Ondansetron tab, ODT, oral solution
- Sancuso (granisetron) patch
- Zuplenz (ondansetron) oral film tab

Substance P/neurokinin 1 (P/NK1) receptor antagonist:
- Apreptiant cap
- Emend (aprepitant) cap, oral suspension
- Varubi (rolapitant) tab

Serotonin type 3 receptor antagonist/ P/NK1 receptor antagonist:
- Akynzeo (palonosetron/netupitant) cap – requires prior authorization

Other:
- Dexamethasone
- Metoclopramide
- Prochlorperazine

Resources:

Syndros (dronabinol). Package Insert. Revised by manufacturer 05/2017. Accessed 05-25-2017.

Syndros (dronabinol). Package Insert. Revised by manufacturer 04/2018. Accessed 07-07-2018.

Badowski ME and Perez SE. Clinical utility of dronabinol in the treatment of weight loss associated with HIV and AIDS. HIV/AIDS research Palliative Care 2016; 8 (Feb 10): 37-45

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.