



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

NEXT REVIEW DATE: 3RD QTR 2012

ORIGINAL EFFECTIVE DATE: 5/20/11
LAST REVIEW DATE: 9/29/11
LAST CRITERIA REVISION DATE: 5/20/11
ARCHIVE DATE:

Adoxa® (doxycycline monohydrate) 6-3-2011
Doryx® (doxycycline hyclate, delayed release)

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. The guideline is not a guarantee of coverage.

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 & 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. The guideline in effect on the date of service will determine coverage.

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

Description:

Adoxa® (doxycycline monohydrate) and Doryx® (doxycycline hyclate) are broad-spectrum antibiotics synthetically derived from oxytetracycline, a tetracycline antibiotic. The antimicrobial mechanism of action of the tetracycline class of antibiotics is thought to be inhibition of protein synthesis resulting in bacteriostatic action against a wide variety of pathogens. The tetracyclines, including doxycycline, have similar antimicrobial spectrum of activity and safety profiles and are used for the treatment of a wide range of aerobic gram-positive, aerobic gram-negative, and anaerobic microorganisms, as well as other pathogens. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Adoxa® and Doryx®, they should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible microorganisms. Cross-resistance of these microorganisms to other tetracyclines is common. Adoxa® 150 mg capsules contain doxycycline monohydrate equivalent to 150 mg of doxycycline for oral administration. Each Doryx® capsule or tablet contains specially coated pellets of doxycycline hyclate equivalent to doxycycline for oral administration.

Precertification:

Precertification* for Adoxa® or Doryx® is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail and mail order prescription benefit. Medications requiring precertification are identified on the following list located on the Internet at

<http://www.azblue.com/pdfs/medications/pharmacy/QIList.pdf>:



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"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions"

This list may also be requested by calling (602) 864-4273 or (800) 232-2345, ext. 4273.

Please refer to this list for other Adoxa® or Doryx® prescription claim limitations where applicable.

- * Precertification will not be required for certain individuals who are already receiving Adoxa® or Doryx®. Members having at least one BCBSAZ paid claim for Adoxa® or Doryx® within the three months preceding the initial effective date of this guideline will not need to obtain precertification.

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.

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Adoxa® (doxycycline monohydrate) and Doryx® (doxycycline hyclate) continued (cont.)

Criteria:

- FDA-approved dosage of Adoxa® or Doryx® is considered **medically necessary** for treatment of individuals (> 8 years of age) with a documented diagnosis of one of the following conditions:
 - Treatment of infection known or strongly suspected to be caused by susceptible microorganism
 - Prevention of infection known or strongly suspected to be caused by susceptible microorganism
 - Adjunctive therapy for severe acne
 - Adjunctive therapy for acute intestinal amebiasis
 - Prophylaxis of malaria
- And (all when applicable)
 - Individual has no hypersensitivity or contraindication to any tetracycline
 - Individual has a non-allergic intolerance to generic doxycycline
 - Individual has an intolerance or contraindication to an excipient in generic doxycycline
 - Individual is not pregnant or likely to become pregnant
 - Individual is not breast feeding

Adoxa® or Doryx® for all other indications not previously listed, are considered experimental or investigational based upon;

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than established alternatives



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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Pharmacy and Therapeutics review	5-5-2011	Adopted guideline
Director Pharmacy Mgmt review	5-4-2011	Development

Criteria Revisions:



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Adoxa® (doxycycline monohydrate) and Doryx® (doxycycline hyclate) Cont.

Resources:

Adoxa package insert (revised March 2008) review on February 17, 2011.

Doryx package insert (revised August 2009) review on February 17, 2011.
