



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

NEXT REVIEW DATE: 3RD QTR 2012

ORIGINAL EFFECTIVE DATE: 6/20/11
LAST REVIEW DATE: 9/29/11
LAST CRITERIA REVISION DATE: NA
ARCHIVE DATE:

Oracea® (doxycycline, USP)

5-5-2011

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:

Oracea® 40mg capsules are filled with two types of doxycycline beads (30 mg immediate release type and 10 mg delayed release type) that provide a 40 mg dose of anhydrous doxycycline, a member of the tetracycline class of antibiotics. The dosage of Oracea® is different from other forms of doxycycline in that Oracea® provides a lower dosage of doxycycline than many other dosage forms available and results in less than the concentrations required to treat bacterial diseases. The Oracea® formulation of doxycycline has not been evaluated as an antibacterial in the treatment of infections. Oracea® should not be used for treating bacterial infections, providing antibacterial prophylaxis, reducing the numbers or eliminating microorganisms associated with any bacterial disease. To reduce the development of resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Oracea® should be used only as indicated.

Precertification:

Precertification* for Oracea® 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>:

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



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

Please refer to this list for other Oracea® prescription claim limitations where applicable.

- * Precertification will not be required for certain individuals who are already receiving Oracea®. Members having at least one BCBSAZ paid claim for Oracea® 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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Oracea® (doxycycline, USP) continued
(cont.) [Date to be determined]

Criteria:

- FDA-approved dosage of Oracea® is considered **medically necessary** for the treatment of inflammatory lesions (papules and pustules) of rosacea in adult individuals (> 18 years of age) with a documented diagnosis of Papulopustular Rosacea
- And (all when applicable):
 - Individual does not have:
 - Generalized erythema of rosacea
 - Erythematotelangiectatic rosacea
 - Phymatous rosacea
 - Ocular rosacea
 - Variants of rosacea:
 - Granulomatous roacea
 - Rosacea fulminans
 - Use is not for treatment or prophylaxis of an infectious process
 - 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 breastfeeding an infant or child

Oracea® for all other indications not previously listed, is 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:



**BlueCross
BlueShield
of Arizona**

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Oracea® (doxycycline, USP) Cont.

Resources:

Oracea package insert (May 2008) review on February 18, 2011.
