



Prior Authorization Approval Criteria

Oracea (doxycycline)

Generic name:	Doxycycline
Brand name:	Oracea
Medication class:	Antibiotic
FDA-approved uses:	Inflammatory lesions (papules and pustules) of rosacea in adult patients.
Available dosage form:	40 mg capsules
Usual dose range:	40 mg once daily
Duration of therapy:	Up to 16 weeks (efficacy beyond that point is not established).
Approximate monthly cost:	About \$150 per month (\$4.94 per capsule) <i>(based on AWP 2006)</i>

Criteria for use *(bullet points below are all inclusive unless otherwise noted):*

- Clinically documented inflammatory lesions (papules and pustules) of rosacea
- Must be 8 years of age or older.
- Failed an immediate release doxycycline product and at least 1 topical treatment.

Cautions:

- Increased risk of overgrowth of nonsusceptible microorganisms, such as fungi. Therefore, Oracea should be used with caution in patients with a history of candidiasis.

Contraindications:

- Hypersensitivity to doxycycline or any of the other tetracyclines

Not approved if:

- Patient only has generalized erythema that is associated with rosacea.
- Have any contraindications to the use of Oracea.

Special considerations:

- There is no evidence that Oracea is superior to its generic doxycycline for treating rosacea. For patients who require antibiotic treatment, generic doxycycline is a less expensive option.
- Oracea showed no meaningful effect for generalized erythema (redness) of rosacea.
- Oracea has not been evaluated for the treatment of the erythematous, telangiectatic, or ocular components of rosacea.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/13/06