

Pharmacy Policy Bulletin

Title: Doxycycline IR/ER (Oracea®)
Policy #: Rx.01.204

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **doxycycline IR/ER (Oracea)** as provided under the member's prescription drug benefit.

Description:

Rosacea is a common, chronic skin disorder that has a multitude of clinical manifestations primarily located on the central face. Adults over the age of 30 are most commonly affected, and women are more commonly affected than men. The pathophysiology of rosacea is not well understood, but possible etiologies include: abnormalities in innate immunity; inflammatory reactions to cutaneous microorganisms; ultraviolet damage; and vascular dysfunction. There are four main subtypes of rosacea, including papulopustular rosacea. Papulopustular rosacea is characterized by acne-like inflammatory papules and pustules typically located on the central face. Unlike acne, comedones do not occur in rosacea; in addition, inflammation may extend outward beyond the follicular unit to form plaques.

Doxycycline IR/ER (Oracea) is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adults. No meaningful effect was demonstrated for generalized erythema (redness) of rosacea.

Doxycycline, a member of the tetracycline class of antibiotics, exerts its therapeutic effect at antimicrobial doses by inhibiting bacterial protein synthesis. When used at sub-antimicrobial doses, doxycycline produces an anti-inflammatory effect which is believed to assist in the treatment of rosacea.

Policy:

INITIAL CRITERIA: Doxycycline IR/ER (Oracea) is approved when ALL of the following are met:

1. Diagnosis of inflammatory lesions (papules and pustules) rosacea; and
2. Patient is 18 years of age or older; and

3. Inadequate response or inability to tolerate generic doxycycline IR 20mg tablets

Initial Authorization duration: 9 months

REAUTHORIZATION CRITERIA: Doxycycline IR/ER (Oracea) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Documentation of continued need for treatment beyond 9 months

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Rosacea: Pathogenesis, clinical features and diagnosis. UpToDate. <https://www.uptodate.com/contents/rosacea-pathogenesis-clinical-features-and-diagnosis>. Updated March 17, 2022. Accessed December 28, 2022.

Oracea® (doxycycline) [package insert]. Fort Worth, TX: Galderma Laboratories; December 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=aa15c93a-ff4c-447a-8a21-96da506d8997&type=display>. Accessed December 28, 2022.

Doxycycline. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at <http://online.lexi.com>. Accessed December 28, 2022.

Rosacea. L Diagnosis and Treatment. American Family Physician Website. <http://www.aafp.org/afp/2015/0801/p187.html>. Published August 1, 2015. Accessed December 28, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Oracea®	doxycycline

Cross References:

Rx.01.33 Off-Label Use

Policy Version Number:	6.00
P&T Approval Date:	December 08, 2022
Policy Effective Date:	April 01, 2023
Next Required Review Date:	December 08, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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