

STEP THERAPY POLICY

- POLICY:** Tetracyclines (Oral) Step Therapy Policy
- Acticlate™ (doxycycline hyclate tablets – Almirall, generic)
 - Avidoxy™ DK Kit (doxycycline monohydrate tablets – Avidas)
 - Doryx® DR (doxycycline hyclate delayed-release tablets – Mayne, generic)
 - Doryx® MPC (doxycycline hyclate delayed-release tablets – Mayne)
 - Doxycycline IR-DR 40 mg capsules (Mayne [authorized generic])
 - Minolira™ (minocycline extended-release tablets – EPI Health)
 - Monodox® (doxycycline monohydrate capsules – Almirall, generic)
 - Morgidox® Kit (doxycycline hyclate capsules – Medimetriks)
 - Oracea™ (doxycycline delayed-release capsules – Galderma, generic)
 - Seysara™ (sarecycline tablets – Almirall)
 - Solodyn® (minocycline hydrochloride extended-release tablets – Bausch Health, generic)
 - Tetracycline tablets and capsules – generic only
 - Targadox™ (doxycycline hyclate tablets – Journey Medical)
 - Vibramycin® (doxycycline hyclate capsules – Pfizer, generic)
 - Ximino™ (minocycline hydrochloride extended-release capsules – Ohm)

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OVERVIEW

Demeclocycline, doxycycline, minocycline, sarecycline and tetracycline are broad-spectrum oral antibiotic agents.^{1-10,20} In general, these medications are FDA-approved to treat a wide **variety of infections caused by gram-negative and gram-positive microorganisms**. Common infections include respiratory tract infections, sexually transmitted infections, skin/skin structure infections, and urinary tract infections; and they can be used in conjunction with other therapies for the management of acne. The tetracycline products are also used in situations where penicillin is contraindicated due to allergy.

There are some doxycycline and minocycline products with unique indications: **Oracea** (brand only) and **doxycycline immediate-release – delayed-release 40 mg capsules** (an authorized generic) are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adults.^{11,12} **Minolira, Seysara, Solodyn, and Ximino** are indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris; Seysara is indicated for use in patients ≥ 9 years of age and Minolira, Solodyn and Ximino are indicated for use in patients ≥ 12 years of age.¹³⁻¹⁶ **Doxycycline 20 mg** tablets are indicated only for use as an adjunct to scaling and root planning to promote attachment level gain and reduce pocket depth in patients with adult periodontitis.¹⁰

In addition, some of the doxycycline and minocycline products are packaged with other items and sold as kits for specific uses. Table 1 summarizes these kits.^{17,18} The doxycycline products in these kits can be purchased separately.

Table 1. Kits that include doxycycline or minocycline antibiotics.^{17,18}

Guidelines

The American Academy of Dermatology guidelines for the management of acne vulgaris (2024) note that the tetracyclines are typically the antibiotics used for this condition.¹⁹ These products have antibacterial as well as anti-inflammatory actions. Doxycycline, minocycline, and sarecycline are similar in efficacy and are more effective than tetracyclines. Systemic antibiotics should be used for the shortest possible duration to minimize the development of bacterial resistance. In addition, systemic antibiotics should not be used as monotherapy; they should be used in conjunction with a topical product.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1:

IR – Immediate release.

Step 2:

DR – Delayed-release; IR – Immediate-release; ER – Extended-release.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

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4. Vibramycin® calcium syrup, Vibramycin® hyclate capsules, Vibramycin® monohydrate powder for oral suspension, Vibra-tabs® [prescribing information]. New York, NY: Pfizer; January 2024.
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16. Ximino™ [prescribing information]. New Brunswick, NJ: Ohm; December 2023.
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