

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 (Owen [brand product])
 - 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)
 - Seysara™ (sarecycline tablets – Almirall)
 - Solodyn® (minocycline hydrochloride extended-release tablets – Bausch Health, generic)
 - 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, and tetracycline are broad-spectrum oral antibiotic agents.¹⁻¹⁰ 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/minocycline products in these kits can be purchased separately.

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

Product	Doxycycline/Minocycline Component	Other Items; Intended Use
Avidoxy™ DK defence™ Kit	doxycycline monohydrate 100 mg	<ul style="list-style-type: none"> • defence acne wash (deep-cleansing foaming emollient acne wash) • defence solare SPF 30+ (sun block) • For management of acne
Morgidox® Kit	doxycycline hyclate 50 or 100 mg	<ul style="list-style-type: none"> • AccuWash® moisturizing cleanser • For management of acne

Guidelines

The American Academy of Dermatology guidelines for the management of acne vulgaris (2016) note that the tetracyclines are typically the antibiotics used for this condition. These products have antibacterial as well as anti-inflammatory actions. Doxycycline and minocycline 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.¹⁹

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:

Product Name and Formulation	Strengths
Demeclocycline tablets	All strengths
Doxycycline hyclate tablets	20 mg, 100 mg
Doxycycline hyclate/ Morgidox capsules	50 mg, 100 mg
Doxycycline monohydrate capsules/tablets	50 mg, 75 mg, 100 mg, 150 mg (tablet only)
Doxycycline monohydrate/Avidoxy tablets	All strengths
Doxycycline monohydrate/Mondoxine capsules	50 mg, 75 mg, 100 mg
Doxycycline monohydrate suspension	All strengths
Minocycline hydrochloride IR capsules	All strengths
Minocycline hydrochloride IR tablets	All strengths
Tetracycline hydrochloride capsules	All strengths

IR – Immediate release.

Step 2:

Product Name and Formulation	Strengths
Acticlate tablets	75mg, 150 mg (brand and generic)
Avidoxy DK Kit	brand
Doryx DR tablets	50 mg, 80 mg, 200 mg (brand and generic)
Doryx MPC tablets	60 mg (brand), 120 mg (brand)
doxycycline hyclate DR tablets	75 mg, 100 mg (generic)
doxycycline hyclate DR tablets/Soloxide	150 mg (generic)
Doxycycline IR-ER 40 mg capsules	Authorized generic
doxycycline monohydrate capsules	150 mg (generic)
Minolira ER tablets	All strengths (brand)
Monodox capsules	All strengths (brand)
Morgidox-Kit	All strengths (brand)
Oracea	All strengths (brand)
Seysara tablets	All strengths (brand)
Solodyn ER tablets	All strengths (brand and generic)
Targadox tablets	50 mg (brand and generic)
Vibramycin cap, suspension, syrup	All strengths (brand)
Ximino ER capsules	All strengths (brand and authorized generic)

IR – Immediate-release; DR – Delayed-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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