



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)

REVIEW DATE: 2/28/2024; selected revision 4/24/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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}

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 (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.

Step 1:

Product Name and Formulation	Strengths
Demeclocycline tablets	150 mg, 300 mg
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	100 mg
Doxycycline monohydrate/Mondoxyne capsules	50 mg, 75 mg, 100 mg
Doxycycline monohydrate suspension	25 mg/ 5 ml
Minocycline hydrochloride IR capsules	50 mg, 75 mg, 100mg
Minocycline hydrochloride IR tablets	50 mg, 75 mg, 100mg
Tetracycline hydrochloride capsules	250 mg, 500 mg

IR – Immediate release.

Step 2:

Product Name and Formulation	Strengths
Acticlate tablets	75mg, 150 mg (brand and generic)
Avidoxy DK Kit	100 mg (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-DR capsules	40 mg (generic)
doxycycline monohydrate capsules	150 mg (generic)
Minolira ER tablets	105 mg, 135 mg (brand)
Monodox capsules	50 mg, 75 mg, 100 mg (brand)
Morgidox-Kit	50 mg, 100 mg (brand)
Oracea	40 mg (brand and authorized generic)
Seysara tablets	60 mg, 100 mg, 150 mg (brand)
Solodyn ER tablets	55 mg, 65 mg, 80 mg, 105 mg, 115 mg (brand and generic)
Targadox tablets	50 mg (brand and generic)
Tetracycline hydrochloride tablets	250 mg, 500 mg (generic)
Vibramycin cap, suspension, syrup	100 mg capsules, 50 mg/5 ml syrup (brand)
Ximino ER capsules	45 mg, 90 mg, 135 mg (brand and authorized generic)

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

Tetracyclines (Oral) Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Demeclocycline tablets [prescribing information]. Bridgewater, NJ: Amneal; May 2018.
2. Acticlate™ tablets [prescribing information]. Exton, PA: Almirall; December 2019.

3. Doryx® tablets [prescribing information]. Greenville, NC: Mayne; July 2022.
4. Vibramycin® calcium syrup, Vibramycin® hyclate capsules, Vibramycin® monohydrate powder for oral suspension, Vibra-tabs® [prescribing information]. New York, NY: Pfizer; January 2024.
5. Dynacin® tablets [prescribing information]. Spring Valley, NY: Par; November 2011.
6. Minocin® pellet-filled capsules [prescribing information]. Bridgewater, NJ: Valeant; January 2019.
7. Monodox® capsules [prescribing information]. Fort Lauderdale, FL: Watson; March 2017.
8. Tetracycline capsules [prescribing information]. Parsippany, NJ: Actavis; November 2018.
9. Targadox™ tablets [prescribing information]. Scottsdale, AZ: Journey Medical; January 2019.
10. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on February 20, 2024. Search terms: tetracycline.
11. Oracea™ delayed-release capsules [prescribing information]. Fort Worth, TX: Galderma; January 2023.
12. Doxycycline IR-DR 40 mg capsules [prescribing information]. Raleigh, NC. Mayne; October 2022.
13. Minolira™ extended release [prescribing information]. Charleston, SC: EPI Health; June 2018.
14. Seysara™ [prescribing information]. Exton, PA: Almirall; March 2023.
15. Solodyn® extended release tablet [prescribing information]. Bridgewater, NJ: Valeant; September 2017.
16. Ximino™ [prescribing information]. New Brunswick, NJ: Ohm; December 2023.
17. Avidoxy™ DK defence Kit. Available at: <http://www.avidaspharma.com/pressrelease004.html>. Accessed on February 20, 2024.
18. Morgidox® Kit [prescribing information]. Fairfield, NJ: Medimetriks; October 2021.
19. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2024 [published online ahead of print].
20. Tetracycline tablets [prescribing information]. Fairmont, WV. Pharmaka Generics. January 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/26/2023
Early Annual Revision	Tetracycline Tablets: Tetracycline tablets (all strengths) were added to Step 2.	2/28/2024
Selected Revision	Doxycycline IR-DR Capsules: Generic doxycycline IR-DR capsules were added to Step 2.	4/24/2024

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.