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Coverage Police	y Number	IP0396

# **Tetracycline Antibiotics**

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## Related Coverage Resources

Sarecycline - (IP0093)
Step Therapy - Legacy Prescription Drug Lists
(Employer Group Plans) - (1803)

#### 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. 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.

### **Overview**

Please refer to Coverage policy IP0093, Sarecycline, for acne vulgaris criteria for sarecycline therapy.

This policy supports medical necessity review for the following Tetracycline antibiotics:

- Acticlate® (doxycycline hyclate 75 mg and 150 mg tablets)
- **Doryx**® (doxycycline hyclate 50 mg, 80 mg, 120 mg, 150 mg, and 200 mg delayed release tablets)
- Doryx MPC® (doxycycline hyclate 60 mg and 120 mg delayed release tablets)
- Doxycycline DR (doxycycline hyclate 50 mg, 75 mg, 80 mg, 100 mg, 150 mg and 200 mg delayed release tablets)
- Minolira™ ER (minocycline 105 mg and 135 mg extended-release tablets)
- **Monodox**® (doxycycline monohydrate 50 mg, 75 mg, and 100 mg capsules)
- **Oracea**® (doxycycline monohydrate 40 mg biphasic release capsules)
- Solodyn<sup>®</sup> (minocycline 55 mg, 65 mg, 80 mg, 105 mg, and 115 mg extended release tablets)
- **TargaDOX**<sup>®</sup> (doxycycline hyclate 50 mg tablets)
- · tetracycline 250 mg, 500 mg tablets
- Vibramycin<sup>®</sup> (doxycycline hyclate 100 mg capsules)

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- Ximino™ ER (minocycline 45 mg, 90 mg, 135 mg extended release capsules)
- Minocycline ER [105 mg, 135 mg extended release tablets (generic for Minolira ER)]
- Minocycline ER [45mg, 90 mg and 135 mg extended release capsules (generic for Ximino)]

Receipt of sample product does not satisfy any criteria requirements for coverage.

## **Medical Necessity Criteria**

Coverage criteria are listed for products in below table:

Employer Plans:		
Product	Criteria	
Acticlate® (doxycycline hyclate 75 mg and 150 mg tablets)	ONE of the following (1 or 2):  1. For a diagnosis of acne and ALL of the following (a, b, and c):  a. The individual has had an inadequate response or is intolerant to ONE of the following (i or ii):  i. doxycycline monohydrate 50 mg or 100 mg ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg  b. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii):  i. minocycline 50 mg, 75 mg or 100 mg ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg  2. For a non-acne diagnosis and ONE of the following (a or b): a. Individual is currently receiving Acticlate b. ALL of the following (i, ii, and iii): i. The individual has had an inadequate response or is intolerant to ONE of the following (1 or 2):  1) doxycycline monohydrate 50 mg or 100 mg 2) doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg ii. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (1 or 2): 1) minocycline 50 mg, 75 mg or 100 mg 2) minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg iii. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg	
Doryx® (doxycycline hyclate 50 mg, 80 mg, 150 mg, and 200 mg delayed release tablets)	<ul> <li>ONE of the following (1 or 2): <ol> <li>For a diagnosis of acne and ALL of the following (a, b, and c):</li> <li>The individual has tried doxycycline hyclate (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</li> <li>The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii): <ol> <li>minocycline 50 mg, 75 mg or 100 mg</li> <li>minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg</li> </ol> </li> <li>The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg</li> </ol></li></ul> <li>For a non-acne diagnosis and ONE of the following (a or b): <ul> <li>Individual is currently receiving Doryx</li> <li>ALL of the following (i, ii, and iii):</li> </ul> </li>	

Product	Criteria	
Doryx MPC® (doxycycline hyclate 60 mg and 120 mg delayed release tablets)	i. The individual has tried doxycycline hyclate (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction  ii. The individual has had an inadequate response, contraindication or is intolerant to ONE of the following (1 or 2):  1) minocycline 50 mg, 75 mg or 100 mg  2) minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  iii. The individual has had an inadequate response, contraindication or is intolerant to tetracycline 250 mg or 500 mg  ONE of the following (1 or 2):  1. For a diagnosis of acne and ALL of the following (a, b, and c): a. The individual has had an inadequate response or is intolerant to ONE of the following (i or ii): i. doxycycline monohydrate 50 mg or 100 mg ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg  b. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii): i. minocycline 50 mg, 75 mg or 100 mg ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg	
	2. For a non-acne diagnosis and ONE of the following (a or b):  a. Individual is currently receiving Doryx  b. ALL of the following (i, ii, and iii):  i. The individual has had an inadequate response or is intolerant to ONE of the following (1 or 2):  1) doxycycline monohydrate 50 mg or 100 mg  2) doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg  ii. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (1 or 2):  1) minocycline 50 mg, 75 mg or 100 mg  2) minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  iii. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg	
Doxycycline DR (doxycycline hyclate 50 mg, 75 mg, 80 mg, 100 mg, 150 mg and 200 mg delayed release tablets)	ONE of the following (1 or 2):  1. For a diagnosis of acne and ALL of the following (a, b, and c):  a. The individual has had an inadequate response or is intolerant to ONE of the following (i or ii):  i. doxycycline monohydrate 50 mg or 100 mg  ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg  b. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii):  i. minocycline 50 mg, 75 mg or 100 mg  ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg  2. For a non-acne diagnosis and ONE of the following (a or b):  a. Individual is currently receiving doxycycline DR  b. ALL of the following (i, ii, and iii):	

Product	Criteria
	<ul> <li>i. The individual has had an inadequate response or is intolerant to ONE of the following (1 or 2): <ol> <li>doxycycline monohydrate 50 mg or 100 mg</li> <li>doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg</li> <li>The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (1 or 2): <ol> <li>minocycline 50 mg, 75 mg or 100 mg</li> <li>minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg</li> <li>The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg</li> </ol> </li> </ol></li></ul>
Minolira™ ER (minocycline 105 mg and 135 mg extended-release tablets)	BOTH of the following (1 and 2):  1. Documented diagnosis of acne 2. ALL of the following (a, b, and c): a. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii): i. doxycycline monohydrate 50 mg or 100 mg ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg b. The individual has had an inadequate response or is intolerant to ONE of the following (i or ii): i. minocycline 50 mg, 75 mg or 100 mg ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg
Monodox® (doxycycline monohydrate 50 mg, 75 mg, and 100 mg capsules)	ONE of the following (1 or 2):  1. For a diagnosis of acne and ALL of the following (a, b, and c):  a. The individual has tried doxycycline monohydrate (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction  b. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii):  i. minocycline 50 mg, 75 mg or 100 mg  ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg  2. For a non-acne diagnosis and ONE of the following (a or b):  a. Individual is currently receiving Monodox  b. ALL of the following (i, ii, and iii):  i. The individual has tried doxycycline monohydrate (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction  ii. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (1 or 2):  1) minocycline 50 mg, 75 mg or 100 mg  2) minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  iii. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg
Oracea® (doxycycline monohydrate 40 mg	BOTH of the following (1 and 2):  1. Documented diagnosis of rosacea 2. ONE of the following (a or b):

Product	Criteria
biphasic release	a. Individual is currently receiving doxycycline monohydrate 40 mg
capsules)	biphasic release capsules
, ,	b. <b>BOTH</b> of the following (i and ii):
	i. The individual has had an inadequate response or is intolerant
	to doxycycline monohydrate 50 mg tablets
	ii. The individual has had an inadequate response,
	contraindication, or is intolerant to minocycline 55 mg extended
	release tablets
Solodyn®	BOTH of the following (1 and 2):
(minocycline 55 mg,	Documented diagnosis of acne
65 mg, 80 mg, 105	2. <b>ALL</b> of the following (a, b, <u>and</u> c):
mg, and 115 mg	a. The individual has had an inadequate response, contraindication, or is
extended release	intolerant to <b>ONE</b> of the following (i <u>or</u> ii):
tablets)	i. doxycycline monohydrate 50 mg or 100 mg
	ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg
	b. The individual has tried minocycline (the bioequivalent generic product)
	AND cannot take due to a formulation difference in the inactive
	ingredient(s) which would result in a significant allergy or serious adverse
	reaction
	c. The individual has had an inadequate response, contraindication, or is
	intolerant to tetracycline 250 mg or 500 mg
TargaDOX <sup>®</sup>	ONE of the following (1 or 2):
(doxycycline	1. For a diagnosis of acne and <b>ALL</b> of the following (a, b, and c):
hyclate 50 mg	a. The individual has had an inadequate response or is intolerant to <b>ONE</b> of
tablets)	the following (i or ii):
	i. doxycycline monohydrate 50 mg or 100 mg
	ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg
	b. The individual has had an inadequate response, contraindication, or is
	intolerant to <b>ONE</b> of the following (i or ii):
	i. minocycline 50 mg, 75 mg or 100 mg
	ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg
	c. The individual has had an inadequate response, contraindication, or is
	intolerant to tetracycline 250 mg or 500 mg
	2. For a non-acne diagnosis <u>and</u> <b>ONE</b> of the following (a <u>or</u> b):
	a. Individual is currently receiving TargaDOX
	b. <b>ALL</b> of the following (i, ii, <u>and</u> iii):
	i. The individual has had an inadequate response or is intolerant to
	ONE of the following (1 or 2):
	1) doxycycline monohydrate 50 mg or 100 mg
	2) doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg
	ii. The individual has had an inadequate response, contraindication, or is intolerant to <b>ONE</b> of the following (1 <u>or</u> 2):
	1) minocycline 50 mg, 75 mg or 100 mg
	2) minocycline 30 mg, 75 mg of 100 mg 2) minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg
	iii. The individual has had an inadequate response, contraindication,
	or is intolerant to tetracycline 250 mg or 500 mg
	2
tetracycline	Tetracycline 250 mg tablet is considered medically necessary when there is an
250 mg tablet	intolerance to tetracycline 250 mg capsules
tetracycline	Tetracycline 500 mg tablet is considered medically necessary when there is an
500 mg tablet	intolerance to tetracycline 500 mg capsules

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Product	Criteria	
	- C.I.SOIIG	
Vibramycin® (doxycycline hyclate 100 mg capsules)	ONE of the following (1 or 2):  1. For a diagnosis of acne and ALL of the following (a, b, and c):  a. The individual has tried doxycycline hyclate (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction  b. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii):  i. minocycline 50 mg, 75 mg or 100 mg  ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg  2. For a non-acne diagnosis and ONE of the following (a or b):  a. Individual is currently receiving Vibramycin  b. ALL of the following (i, ii, and iii):  i. The individual has tried doxycycline hyclate (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction  ii. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (1 or 2):  1) minocycline 50 mg, 75 mg or 100 mg  2) minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  iii. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg	
Ximino™ ER (minocycline 45 mg, 90 mg, 135 mg extended release capsules)	BOTH of the following (1 and 2):  1. Documented diagnosis of acne  2. ALL of the following (a, b, and c):  a. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii):  i. doxycycline monohydrate 50 mg or 100 mg  ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg  b. The individual has had an inadequate response or is intolerant to ONE of the following (i or ii):  i. minocycline 50 mg, 75 mg or 100 mg  ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg	
Minocycline ER (generic for Minolira ER) 105 mg, 135 mg extended release tablets	BOTH of the following (1 and 2):  1. Documented diagnosis of acne  2. ALL of the following (a, b, and c):  a. The individual has had an inadequate response, contraindication, or is intolerant to ONE of the following (i or ii):  i. doxycycline monohydrate 50 mg or 100 mg  ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg  b. The individual has had an inadequate response or is intolerant to ONE of the following (i or ii):  i. minocycline 50 mg, 75 mg or 100 mg  ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg  c. The individual has had an inadequate response, contraindication, or is intolerant to tetracycline 250 mg or 500 mg	

Product	Criteria	
	Note: May require step therapy on the Legacy formulary.	
Minocycline ER	BOTH of the following (1 and 2):	
(generic for Ximino)	Documented diagnosis of acne	
45 mg, 90 mg and	2. ALL of the following (a, b, and c):	
135 mg extended	d. The individual has had an inadequate response, contraindication, or is	
release capsules	intolerant to <b>ONE</b> of the following (i <u>or</u> ii):	
	i. doxycycline monohydrate 50 mg or 100 mg	
	ii. doxycycline hyclate 50 mg, 75 mg, 100 mg, or 150 mg	
	e. The individual has had an inadequate response or is intolerant to <b>ONE</b> of	
	the following (i <u>or</u> ii):	
	i. minocycline 50 mg, 75 mg or 100 mg	
	ii. minocycline ER 55 mg, 65 mg, 80 mg, 105 mg or 115 mg	
	f. The individual has had an inadequate response, contraindication, or is	
	intolerant to tetracycline 250 mg or 500 mg	
	Nata Marina da di santa di san	
	Note: May require step therapy on the Legacy formulary.	

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

### **Reauthorization Criteria**

Tetracycline antibiotics are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

### **Authorization Duration**

Initial approval duration: up to 6 months.

Reauthorization approval duration: up to 12 months.

### **Conditions Not Covered**

Tetracycline antibiotics are considered experimental, investigational or unproven for **ANY** other use.

## Background

#### **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. 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  $\geq 9$  years of age and Minolira, Solodyn and Ximino are indicated for use in patients  $\geq 12$  years of age. Doxycycline 20 mg tablets are indicated only for use as an

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adjunct to scaling and root planning to promote attachment level gain and reduce pocket depth in patients with adult periodontitis.<sup>10</sup>

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. 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 monohyclate 100 mg	<ul> <li>defence acne wash (deep-cleansing foaming emollient acne wash)</li> <li>defence solare SPF 30+ (sun block)</li> <li>For management of acne</li> </ul>
Morgidox <sup>®</sup> Kit	doxycycline hyclate 50 or 100 mg	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. 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.

### References

- 1. Demeclocycline tablets [prescribing information]. Bridgewater, NJ: Amneal; May 2018.
- Acticlate<sup>™</sup> 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.
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- 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.
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