



# Louisiana

## Tetracyclines (oral)

Policy # 00341

Original Effective Date: 02/20/2013

Current Effective Date: 01/01/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### **For Patients With "Step Therapy" (generic before brand) ONLY:**

Based on review of available data, the Company may consider brand name oral tetracyclines including, but not limited to Acticlate<sup>®†</sup> (doxycycline hyclate), Doryx<sup>®†</sup> (doxycycline hyclate), Oracea<sup>®†</sup> (doxycycline), Targadox<sup>®†</sup> (doxycycline hyclate), Ximino<sup>™†</sup> (minocycline), Minolira<sup>™†</sup> (minocycline), Seysara<sup>™†</sup> (sarecycline), and Solodyn<sup>®†</sup> (minocycline) to be **eligible for coverage\*\*** when ONE of the below patient selection criteria is met:

### **Patient Selection Criteria**

Coverage eligibility will be considered for brand name oral tetracyclines when ONE of the following criteria is met:

- Patient has tried and failed one generic oral tetracycline (e.g. demeclocycline, doxycycline, minocycline, tetracycline); OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral tetracyclines when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.\*\***

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## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### **For Patients With "Prior Authorization" ONLY:**

Based on review of available data, the Company may consider Ximino (minocycline), Minolira (minocycline), Seysara (sarecycline), Solodyn (minocycline), minocycline extended release tablets, Acticlate (doxycycline hyclate), coremino (minocycline), doxycycline hyclate delayed release tablets, Doryx (doxycycline hyclate), Doryx MPC (doxycycline hyclate), doxycycline monohydrate 75 mg and 150 mg capsules, Monodox<sup>®</sup> (doxycycline monohydrate), monodoxyne<sup>™</sup> nl (doxycycline) 75 mg capsules, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, Targadox (doxycycline hyclate), Oracea (doxycycline), and branded doxycycline immediate-release-delayed release 40 mg to be **eligible for coverage\*\*** when the patient selection criteria are met:

### Patient Selection Criteria

Coverage eligibility will be considered for Ximino (minocycline), Minolira (minocycline), Seysara (sarecycline), Solodyn (minocycline), minocycline extended release tablets, Acticlate (doxycycline hyclate), coremino (minocycline), doxycycline hyclate delayed release tablets, Doryx (doxycycline hyclate), Doryx MPC (doxycycline hyclate), doxycycline monohydrate 75 mg and 150 mg capsules, Monodox (doxycycline monohydrate), monodoxyne nl (doxycycline) 75 mg capsules, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, Targadox (doxycycline hyclate), Oracea (doxycycline), and branded doxycycline immediate-release-delayed release 40 mg when the following criteria are met:

- For Ximino, Minolira, Seysara, Solodyn, and minocycline extended release tablet requests **ONLY:**
  - If the requested drug is Seysara, the patient is 9 years of age or older. If the requested drug is Ximino, Minolira, Solodyn, or minocycline extended release tablet, the patient is 12 years of age or older; **AND**
  - Patient has a diagnosis of non-nodular moderate to severe acne vulgaris; **AND**
  - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred **GENERIC** oral minocycline product (e.g., immediate release minocycline) for at

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- least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Patient has tried and failed (e.g. intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - Patient is currently and will continue using an over the counter or prescription generic benzoyl peroxide product unless there is clinical evidence or patient history that suggests the use of over the counter or prescription generic benzoyl peroxide treatments will be ineffective or cause an adverse reaction to the patient.  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - For Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, and Targadox requests:
    - Patient has a diagnosis of acne vulgaris and ALL of the following
      - Patient has tried and failed (e.g. intolerance or inadequate response) a preferred GENERIC oral minocycline product (e.g., immediate release minocycline) for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
      - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

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*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

- Patient is currently and will continue using an over the counter or prescription generic benzoyl peroxide product unless there is clinical evidence or patient history that suggests the use of over the counter or prescription generic benzoyl peroxide treatments will be ineffective or cause an adverse reaction to the patient; OR  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Requested drug will be used for prophylaxis of malaria; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; OR  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Requested drug will be used for another medical condition (e.g., Rickettsial infection, sexually transmitted infections, respiratory tract infections, specific bacterial infections, ophthalmic infections, anthrax, selected infections when penicillin is contraindicated, acute intestinal amebiasis); AND ALL of the following:
  - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - Patient has tried and failed (e.g., intolerance or inadequate response) a DIFFERENT ingredient preferred GENERIC oral tetracycline product (e.g.,

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immediate-release minocycline) unless there is clinical evidence or patient history that suggests the use of a DIFFERENT ingredient preferred GENERIC oral tetracycline product will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

- For Oracea and Branded Doxycycline immediate release-delayed release 40 mg requests ONLY:
  - Patient has a diagnosis of inflammatory lesions (papules and pustules) of rosacea; AND
  - Patient is 18 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) one of the following topical treatments: GENERIC metronidazole, GENERIC azelaic acid 15% gel, Finacea<sup>®†</sup> 15% foam unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
    - (Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO preferred generic immediate release doxycycline and minocycline agents for 12 weeks each unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
    - (Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Ximino (minocycline), Minolira (minocycline), Seysara (sarecycline), Solodyn, or minocycline extended release tablet when the patient is not using an over the counter or prescription generic benzoyl peroxide product or has not tried and failed a preferred generic oral minocycline product for at least 12 weeks AND a preferred generic oral doxycycline product for an additional 12 weeks to be **not medically necessary**.\*\*

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Based on review of available data, the Company considers the use of Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, or Targadox for acne when the patient is not using an over the counter or prescription generic benzoyl peroxide product or has not tried and failed a preferred generic oral minocycline product for at least 12 weeks AND a preferred generic oral doxycycline product for an additional 12 weeks to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, or Targadox for prophylaxis of malaria when the patient has not tried and failed a preferred generic oral doxycycline product to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, or Targadox for the treatment of infections when the patient has not tried and failed a preferred generic oral doxycycline product and another preferred generic oral tetracycline product to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Oracea or branded doxycycline immediate release-delayed release 40 mg when the patient has not tried and failed a preferred generic topical treatment and TWO preferred generic immediate release doxycycline and minocycline agents for 12 weeks each to be **not medically necessary.\*\***

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of Ximino (minocycline), Minolira (minocycline), Seysara (sarecycline), Solodyn, or minocycline extended release tablets for any indication other than the treatment of non-nodular acne vulgaris or for patients younger than the

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FDA approved age for the respective drug (i.e. 9 years for Seysara and 12 years for Ximino, Minolira, Solodyn, and minocycline extended release tablets) to be **investigational**.\*

Based on review of available data, the Company considers the use of Oracea or branded Doxycycline immediate release-delayed release 40 mg for any indication other than the treatment of inflammatory lesions of rosacea or for patients younger than 18 years of age to be **investigational**.\*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### **For Patients With BOTH "Prior Authorization" AND "Step Therapy":**

Based on review of available data, the Company may consider brand name oral tetracyclines including, but not limited to Acticlate (doxycycline hyclate), Doryx (doxycycline hyclate), Oracea (doxycycline), Targadox (doxycycline hyclate), Ximino (minocycline), Minolira (minocycline), Seysara (sarecycline), Solodyn (minocycline), minocycline extended release tablets, coremino (minocycline), doxycycline hyclate delayed release tablets, Doryx MPC (doxycycline hyclate), doxycycline monohydrate 75 mg and 150 mg capsules, Monodox (doxycycline monohydrate), monodoxyne nl (doxycycline) 75 mg capsules, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, and branded doxycycline immediate-release-delayed release 40 mg to be **eligible for coverage\*\*** when the patient selection criteria are met:

### **Patient Selection Criteria**

Coverage eligibility will be considered for brand name and non-preferred generic oral tetracyclines when ALL of the specific drug's criteria are met:

- For Ximino, Minolira, Seysara, Solodyn, and minocycline extended release tablet requests ONLY:
  - If the requested drug is Seysara, the patient is 9 years of age or older. If the requested drug is Ximino, Minolira, Solodyn, or minocycline extended release tablet, the patient is 12 years of age or older; AND
  - Patient has a diagnosis of non-nodular moderate to severe acne vulgaris; AND

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- Patient has tried and failed (e.g. intolerance or inadequate response) a preferred GENERIC oral minocycline product (e.g., immediate release minocycline) for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Patient has tried and failed (e.g. intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Patient is currently and will continue using an over the counter or prescription generic benzoyl peroxide product unless there is clinical evidence or patient history that suggests the use of over the counter or prescription generic benzoyl peroxide treatments will be ineffective or cause an adverse reaction to the patient. *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- For Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, and Targadox requests:
  - Patient has a diagnosis of acne vulgaris and ALL of the following
    - Patient has tried and failed (e.g. intolerance or inadequate response) a preferred GENERIC oral minocycline product (e.g., immediate release minocycline) for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
    - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) for at least 12 weeks unless there is clinical evidence or patient

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history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

- Patient is currently and will continue using an over the counter or prescription generic benzoyl peroxide product unless there is clinical evidence or patient history that suggests the use of over the counter or prescription generic benzoyl peroxide treatments will be ineffective or cause an adverse reaction to the patient; OR

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

- Requested drug will be used for prophylaxis of malaria; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; OR

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Requested drug will be used for another medical condition (e.g., Rickettsial infection, sexually transmitted infections, respiratory tract infections, specific bacterial infections, ophthalmic infections, anthrax, selected infections when penicillin is contraindicated, acute intestinal amebiasis); AND ALL of the following:
  - Patient has tried and failed (e.g., intolerance or inadequate response) a preferred GENERIC oral doxycycline product (e.g., immediate release doxycycline) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

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- Patient has tried and failed (e.g., intolerance or inadequate response) a DIFFERENT ingredient preferred GENERIC oral tetracycline product (e.g., immediate-release minocycline) unless there is clinical evidence or patient history that suggests the use of a DIFFERENT ingredient preferred GENERIC oral tetracycline product will be ineffective or cause an adverse reaction to the patient.  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- For Oracea and Branded Doxycycline immediate release-delayed release 40 mg requests ONLY:
  - Patient has a diagnosis of inflammatory lesions (papules and pustules) of rosacea; AND
  - Patient is 18 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) one of the following topical treatments: GENERIC metronidazole, GENERIC azelaic acid 15% gel, Finacea 15% foam unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO preferred generic immediate release doxycycline and minocycline agents for 12 weeks each unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- For all other brand name oral tetracycline requests:
  - Patient has tried and failed one generic oral tetracycline (e.g. demeclocycline, doxycycline, minocycline, tetracycline); OR
  - There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

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*(Note: The criteria for the trial and failure of other products are additional Company requirements for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Ximino (minocycline), Minolira (minocycline), or Seysara (sarecycline) when the patient is not using an over the counter or prescription generic benzoyl peroxide product or has not tried and failed a preferred generic oral minocycline product for at least 12 weeks AND a preferred generic oral doxycycline product for an additional 12 weeks to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, or Targadox for acne when the patient is not using an over the counter or prescription generic benzoyl peroxide product or has not tried and failed a preferred generic oral minocycline product for at least 12 weeks AND a preferred generic oral doxycycline product for an additional 12 weeks to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, or Targadox for prophylaxis of malaria when the patient has not tried and failed a preferred generic oral doxycycline product to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsule, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, or Targadox for the treatment of infections when the patient has not tried and failed a preferred generic oral doxycycline product and another preferred generic oral tetracycline product to be **not medically necessary.\*\***

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Based on review of available data, the Company considers the use of Oracea or branded Doxycycline immediate release-delayed release 40 mg capsules when the patient has not tried and failed a preferred generic topical treatment and TWO preferred generic immediate release doxycycline and minocycline agents for 12 weeks each to be **not medically necessary**.\*\*

Based on review of available data, the Company considers the use of brand name oral tetracyclines (besides those specified above) when the patient has not tried and failed one generic oral tetracycline (e.g. demeclocycline, doxycycline, minocycline, tetracycline) to be **not medically necessary**.\*\*

## **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of Ximino (minocycline), Minolira (minocycline), Seysara (sarecycline), Solodyn, or minocycline extended release tablets for any indication other than the treatment of non-nodular acne vulgaris or for patients younger than the FDA approved age for the respective drug (i.e. 9 years for Seysara and 12 years for Ximino, Minolira, Solodyn, and minocycline extended release tablets) to be **investigational**.\*

Based on review of available data, the Company considers the use of Oracea or branded Doxycycline immediate release-delayed release 40 mg for any indication other than the treatment of inflammatory lesions of rosacea or for patients younger than 18 years of age to be **investigational**.\*

## **Background/Overview**

Demeclocycline, doxycycline, minocycline, sarecycline, and tetracycline are broad spectrum oral antibiotic agents. In general, these medications are all Food and Drug Administration (FDA)-indicated to treat a wide variety of infections such as those caused by gram negative and positive microorganisms; in adjunct to other therapies for severe acne; and in situations where penicillin is contraindicated due to allergy.

Ximino, Minolira, and Solodyn are extended release formulations of minocycline that are indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. None of these formulations demonstrated any effect on non-inflammatory acne

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lesions and they have not been evaluated in the treatment of infections. Seysara is a more narrow spectrum tetracycline antibiotic that is also indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris. Unlike the extended release minocycline products, Seysara is approved for patients 9 years of age and older. Many formulations of oral doxycycline are available and can be used for the treatment of acne vulgaris. According to the American Academy of Dermatology, systemic antibiotics should be used in combination with topical agents for the treatment of acne vulgaris. Examples of topical acne medications include benzoyl peroxide, adapalene, and sodium sulfacetamide.

Oral doxycycline is used for the treatment of many conditions, including, but not limited to acne, rosacea, Rickettsial infections, sexually transmitted infections, respiratory tract infections, specific bacterial infections, ophthalmic infections, anthrax, certain infections when penicillin is contraindicated, and acute intestinal amebiasis. It can also be used for malaria prophylaxis. There are numerous strengths and formulations of doxycycline available.

## **Rationale/Source**

Oral tetracyclines are available in a wide variety of dosage forms including immediate release products, extended release products, tablets and capsules of various strengths, generic products, brand products, and authorized (or branded) generic products. Although these products may not be directly interchangeable, there are many products that contain the same ingredients and are commonly used for the same indications. Additionally, these products have not been compared to each other in clinical trials, so no claims of superior efficacy can be made. The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests the more cost-effective products will be ineffective or cause an adverse reaction to the patient. In the absence of this caveat, there is no advantage of using a more costly tetracycline formulation over the generic or lower-cost options.

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## **Policy History**

Original Effective Date: 02/20/2013

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- |            |   |
|------------|---|
| 02/07/2013 | Medical Policy Committee review   |
| 02/20/2013 | Medical Policy Implementation Committee approval. New policy.   |
| 02/06/2014 | Medical Policy Committee review   |
| 02/19/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 04/02/2015 | Medical Policy Committee review   |
| 04/20/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 04/07/2016 | Medical Policy Committee review   |
| 04/20/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 04/06/2017 | Medical Policy Committee review   |
| 04/19/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 04/05/2018 | Medical Policy Committee review   |
| 04/18/2018 | Medical Policy Implementation Committee approval. Removed the following obsolete branded drugs from step 2: Declomycin (demeclocycline), Vibra-tabs (doxycycline), and Sumycin (tetracycline). Added the following branded drugs to |

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step 2: Acticlate (doxycycline hyclate), Oracea (doxycycline), Ximino (minocycline), and Targadox (doxycycline hyclate). Also added PA criteria for Ximino and separated policy into step only, step/PA, and PA only to address the PA added to Ximino.

02/07/2019 Medical Policy Committee review

02/20/2019 Medical Policy Implementation Committee approval. Added Minolira to the policy with PA criteria matching Ximino.

06/06/2019 Medical Policy Committee review

06/19/2019 Medical Policy Implementation Committee approval. Added Seysara to the policy.

06/04/2020 Medical Policy Committee review

06/10/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/01/2020 Medical Policy Committee review

10/07/2020 Medical Policy Implementation Committee approval. Added the following products to the policy with prior authorization criteria: Solodyn, minocycline extended release tablets, Acticlate, coremino, doxycycline hyclate delayed release tablets, Doryx, Doryx MPC, doxycycline monohydrate 75 mg and 150 mg capsules, Monodox, monodoxyne nl 75 mg capsules, doxycycline hyclate 50 mg, 75 mg, and 150 mg tablets, Targadox, Oracea, and branded doxycycline immediate-release-delayed release 40 mg. Removed obsolete product, Adoxa. Updated relevant background information.

Next Scheduled Review Date: 10/2021

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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