



Louisiana

Tetracyclines (oral)

Policy # 00341

Original Effective Date: 02/20/2013

Current Effective Date: 04/18/2018

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^{®†} (doxycycline hyclate), Adoxa^{®‡ †} (doxycycline), Doryx^{®‡ †} (doxycycline hyclate), Oracea^{®‡} (doxycycline), Targadox^{®‡} (doxycycline hyclate), Ximino^{™‡} (minocycline), and, Solodyn^{®‡ †} (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:

- The 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**.**

For Patients With "Prior Authorization" ONLY:

Based on review of available data, the Company may consider Ximino (minocycline) to be **eligible for coverage** when the patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Ximino (minocycline) when the following criteria are met:

- The patient is 12 years of age or older; AND
- The patient has a diagnosis of non-nodular moderate to severe acne vulgaris; AND
- The patient has tried and failed (e.g. intolerance or inadequate response) a **GENERIC** oral minocycline product 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).*

- The patient has tried and failed (e.g. intolerance or inadequate response) a GENERIC oral doxycycline product 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).*

- The 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).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Ximino (minocycline) when the patient is not using an over the counter or prescription generic benzoyl peroxide product or has not tried and failed generic oral minocycline product for at least 12 weeks AND a generic oral doxycycline product for an additional 12 weeks 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) for patients younger than 12 years of age or for any indication other than the treatment of non-nodular acne vulgaris to be **investigational.***

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), Adoxa^{®‡ †} (doxycycline), Doryx^{®‡ †} (doxycycline hyclate), Oracea^{®‡} (doxycycline), Targadox^{®‡} (doxycycline hyclate), Ximino^{™‡} (minocycline), and, Solodyn^{®‡ †} (minocycline) to be **eligible for coverage** when the patient selection criteria is met:

Patient Selection Criteria

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

- For Ximino requests ONLY:
 - o The patient is 12 years of age or older; AND
 - o The patient has a diagnosis of non-nodular moderate to severe acne vulgaris; AND

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- o The patient has tried and failed (e.g. intolerance or inadequate response) a generic oral minocycline product 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).*
- o The patient has tried and failed (e.g. intolerance or inadequate response) a generic oral doxycycline product 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).*
- o The 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 all other brand name oral tetracycline requests:
 - o The patient has tried and failed one generic oral tetracycline (e.g. demeclocycline, doxycycline, minocycline, tetracycline); OR
 - o There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.
*(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) when the patient is not using an over the counter or prescription generic benzoyl peroxide product or has not tried and failed generic oral minocycline product for at least 12 weeks AND a 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 brand name oral tetracyclines (besides Ximino [minocycline]) when the patient has not tried and failed one generic oral tetracycline (e.g. demeclocycline, doxycycline, minocycline, tetracycline) to be **not medically necessary.****

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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) for patients younger than 12 years of age or for any indication other than the treatment of non-nodular acne vulgaris to be **investigational**.*

Background/Overview

Demeclocycline, doxycycline, minocycline, 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 is an extended release formulation of minocycline that is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. It did not demonstrate any effect on non-inflammatory acne lesions and has not been evaluated in the treatment of infections. According to the American Academy of Dermatology, systemic antibiotics (such as Ximino) 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.

Rationale/Source

Concerning step therapy: the patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a brand name oral tetracycline over the available generic oral tetracyclines. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

Concerning prior authorization: the efficacy of Ximino was shown in two 12-week, multi-center, randomized, double-blind, placebo-controlled studies. Ximino has not demonstrated superiority to generically available tetracyclines such as minocycline or doxycycline which are the standard of care for the treatment of inflammatory acne vulgaris. Generic tetracycline products offer an equally efficacious, yet cost effective alternative to this branded product.

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Policy History

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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 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. |

Next Scheduled Review Date: 04/2019

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*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 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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