Topical Antifungals

Policy # 00527
Original Effective Date: 01/01/2017
Current Effective Date: 10/14/2024

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.*

Based on review of available data, the Company may consider the following topical antifungal products: Mentax®‡ 1% (butenafine) cream, Ecoza™‡ 1% (econazole) foam, Luzu®‡ 1% (luliconazole) cream, branded Luliconazole 1% cream, Oxistat®‡ 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, oxiconazole 1% cream, Ertaczo®‡ 2% (sertaconazole) cream, Exelderm®‡ 1% (sulconazole) cream, branded Sulconazole 1% cream, Exelderm 1% (sulconazole) solution, branded Sulconazole 1% solution, Naftin®‡ 1% (naftifine) gel, naftifine 1% gel, Naftin 2% (naftifine) gel, naftifine 2% gel, Naftin 2% (naftifine) cream, naftifine 1% cream, naftifine 2% cream, Jublia®‡ 10% (efinaconazole) solution, Kerydin®‡ 5% (tavaborole) solution, tavaborole 5% solution, Extina®‡ 2% (ketoconazole) foam, Xolegel®‡ 2% (ketoconazole) gel, Loprox®‡ 1% (ciclopirox) shampoo, Loprox 0.77% (ciclopirox) cream, and Loprox (ciclopirox) 0.77% suspension to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Mentax 1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, branded Luliconazole 1% cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, oxiconazole 1% cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, branded Sulconazole 1% cream, Exelderm 1% (sulconazole) solution, branded Sulconazole 1% solution, Naftin 1% (naftifine) gel, naftifine 1% gel, Naftin 2% (naftifine) gel, naftifine 2% gel, Naftin 2% (naftifine) cream, naftifine 1% cream, naftifine 2% cream, Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, tavaborole 5%

solution, Extina 2% (ketoconazole) foam, Xolegel 2% (ketoconazole) gel, Loprox 1% (ciclopirox) shampoo, Loprox 0.77% (ciclopirox) cream, or Loprox (ciclopirox) 0.77% suspension when the following criteria are met for the requested drug:

- For Mentax 1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, branded Luliconazole 1% cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, oxiconazole 1% cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, branded Sulconazole 1% cream, Exelderm 1% (sulconazole) solution, branded Sulconazole 1% solution, Naftin 1% (naftifine) gel, naftifine 1% gel, Naftin 2% (naftifine) gel, naftifine 2% gel, Naftin 2% (naftifine) cream, naftifine 1% cream, or naftifine 2% cream requests:
    - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following generic prescription topical antifungal products (ketoconazole, clotrimazole, econazole) unless there is clinical evidence or patient history that suggests the use of two of the following generic prescription topical antifungal products (ketoconazole, clotrimazole, econazole) will be ineffective or cause an adverse reaction to the patient.
- For Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, or tavaborole 5% solution requests:
    - Patient has tried and failed (e.g., intolerance or inadequate response) a 3 month course of treatment with generic oral terbinafine OR generic oral itraconazole unless there is clinical evidence or patient history that suggests the use of generically available oral terbinafine or generically available oral itraconazole will be ineffective or cause an adverse reaction to the patient; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) a 48 week course of treatment with generic topical ciclopirox unless there is clinical evidence or patient history that suggests the use of generically available topical ciclopirox will be ineffective or cause an adverse reaction to the patient.
- For Xolegel 2% (ketoconazole) gel, Loprox 1% (ciclopirox) shampoo, or Extina 2% (ketoconazole) foam requests:
    - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following generic prescription topical antifungal products for seborrheic dermatitis (ketoconazole foam, ciclopirox gel/shampoo) unless there is clinical evidence or patient history that suggests the use of two of the following generic

prescription topical antifungal products for seborrheic dermatitis (ketoconazole foam, ciclopirox gel/shampoo) will be ineffective or cause an adverse reaction to the patient.

- For Loprox 0.77% (ciclopirox) cream requests:
  - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following generic prescription topical antifungal products (ketoconazole, clotrimazole, econazole) unless there is clinical evidence or patient history that suggests the use of two of the following generic prescription topical antifungal products (ketoconazole, clotrimazole, econazole) will be ineffective or cause an adverse reaction to the patient; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent ciclopirox 0.77% cream unless there is clinical evidence or patient history that suggests the use of the generic equivalent ciclopirox 0.77% cream will be ineffective or cause an adverse reaction to the patient.
- For Loprox (ciclopirox) 0.77% suspension requests:
  - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following generic prescription topical antifungal products (ketoconazole, clotrimazole, econazole) unless there is clinical evidence or patient history that suggests the use of two of the following generic prescription topical antifungal products (ketoconazole, clotrimazole, econazole) will be ineffective or cause an adverse reaction to the patient; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent ciclopirox 0.77% suspension unless there is clinical evidence or patient history that suggests the use of the generic equivalent ciclopirox 0.77% suspension 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 Mentax 1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, branded Luliconazole 1% cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, oxiconazole 1% cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, branded Sulconazole 1% cream, Exelderm 1% (sulconazole) solution, branded Sulconazole 1% solution, Naftin 1% (naftifine) gel, naftifine 1% gel, Naftin 2% (naftifine) gel, naftifine 2% gel, Naftin 2% (naftifine) cream, naftifine

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1% cream, naftifine 2% cream, Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, tavaborole 5% solution, Extina 2% (ketoconazole) foam, Xolegel 2% (ketoconazole) gel, Loprox 1% (ciclopirox) shampoo, Loprox 0.77% (ciclopirox) cream, or Loprox (ciclopirox) 0.77% suspension WITHOUT clinical evidence or patient history that suggests the use of the preferred generic products mentioned in the patient selection criteria for each requested drug will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

Schematic

Non-Preferred Products	Preferred Products
Mentax 1% cream Ecoza 1% foam Luzu 1% cream Branded Luliconazole 1% cream Oxistat 1% lotion Oxistat 1% cream oxiconazole 1% cream Ertaczo 2% cream Exelderm 1% cream Branded Sulconazole 1% cream Exelderm 1% solution Branded Sulconazole 1% solution Naftin 1% gel naftifine 1% gel Naftin 2% gel naftifine 2% gel Naftin 2% cream naftifine 1% cream naftifine 2% cream	Generic topical ketoconazole Generic topical clotrimazole Generic topical econazole
Jublia 10% solution Kerydin 5% solution tavaborole 5% solution	Generic oral terbinafine Generic oral itraconazole Generic topical ciclopirox solution

Xolegel 2% gel Extina 2% foam Loprox 1% shampoo	Generic ketoconazole foam Generic ciclopirox gel/shampoo
Loprox 0.77% cream	Generic topical ketoconazole Generic topical clotrimazole Generic topical econazole Generic ciclopirox 0.77% cream[#]
Loprox 0.77% suspension	Generic topical ketoconazole Generic topical clotrimazole Generic topical econazole Generic ciclopirox 0.77% suspension[#]

[#]Generic equivalent must be tried and failed

Background/Overview

The majority of the products mentioned in this policy are approved for the treatment of tinea infections (versicolor, pedis, corporis, and cruris). There are a variety of topical generic products (ketoconazole, clotrimazole, econazole) that are approved for use in these conditions that are equally as effective, yet substantially less expensive than the available brand name topical products. Jublia and Kerydin (and its generic equivalent) are approved for the treatment of onychomycoses. Other more cost effective and more clinically efficacious products for the treatment of onychomycoses include generic agents such as ciclopirox, terbinafine, or itraconazole. Xolegel and Extina are approved for seborrheic dermatitis, yet again there are other products that are available in generic form to treat this condition. There are also various products in this policy that have a generic equivalent. Generic equivalents are interchangeable with the branded reference product and offer a more cost-effective option versus the branded reference product.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available alternatives listed in this policy will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any caveat mentioned, there is no advantage of using Mentax 1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, branded Luliconazole 1% cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, oxiconazole 1% cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, branded Sulconazole 1% cream, Exelderm 1% (sulconazole) solution, branded Sulconazole 1% solution, Naftin 1% (naftifine) gel, naftifine 1% gel, Naftin 2% (naftifine) gel, naftifine 2% gel, Naftin 2% (naftifine) cream, naftifine 1% cream, naftifine 2% cream, Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, tavaborole 5% solution, Extina 2% (ketoconazole) foam, Xolegel 2% (ketoconazole) gel, Loprox 1% (ciclopirox) shampoo, Loprox 0.77% (ciclopirox) cream, or Loprox (ciclopirox) 0.77% suspension over the available generic alternatives mentioned in this policy.

References

1. Mentax [package insert]. Bertek Pharmaceuticals. San Antonio, Texas. Updated 2001.
2. Ecoza [package insert]. Quinnova Pharamceuticals. Jamison, Pennsylvania. Updated October 2013.
3. Luzu [package insert]. Valeant Pharmaceuticals. Bridgewater, New Jersey. Updated November 2013
4. Oxistat cream/lotion [package insert]. GlaxoSmithKline. Pittsburgh, Pennsylvania. Updated 2004.
5. Ertaczo [package insert]. Valeant Pharmaceuticals. Bridgewater, New Jersey. Updated January 2014.
6. Exelderm cream. [package insert]. Westwood Squibb. Buffalo, New York. Updated 2003.
7. Exelderm solution [package insert]. Ranbaxy. Jacksonville, Florida. Updated 2009.
8. Naftin gel [package insert]. Merz Pharmaceuticals. Greensboro, North Carolina. Updated October 2014.
9. Naftin cream [package insert]. Merz Pharmaceuticals. Greensboro, North Carolina. Updated October 2014.
10. Jublia [package insert].Valeant Pharmaceuticals. Bridgewater, New Jersey. Updated February 2015.

11. Kerydin [package insert]. Anacor Pharmaceuticals. Palo Alto, California. Updated February 2015.
12. Xolegel [package insert]. Aqua Pharmaceuticals. West Chester, Pennsylvania. Updated May 2012.
13. Dermatophyte (Tinea) infections. UpToDate. Updated November 2015.
14. Onchomycosis Management. UpToDate. Updated May 2016.
15. Seborrheic Dermatitis. UpToDate. Updated December 2015.
16. Extina [package insert]. Prestium Pharma. Newtown, Pennsylvania. Updated June 2013.
17. Luliconazole [package insert]. Valeant Pharmaceuticals. Bridgewater, New Jersey. Updated June 2018.
18. Sulconazole nitrate cream/solution [package insert]. JG Pharma. Scottsdale, Arizona. Updated February 2020.
19. naftifine 1% gel [package insert]. Amneal Pharmaceuticals. Bridgewater, New Jersey. Updated November 2018.
20. Loprox Cream [package insert]. Medimetriks Pharmaceuticals, Inc. Fairfield, New Jersey. Updated January 2016.
21. Loprox Suspension [package insert]. Medimetriks Pharmaceuticals, Inc. Fairfield, New Jersey. Updated March 2016.
22. Loprox Shampoo [package insert]. Bausch Health US, LLC. Bridgewater, New Jersey. Updated May 2019.

Policy History

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09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. New policy.
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Removed branded naftifine cream from the policy as it is now generic
07/03/2019	Medical Policy Committee review

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07/18/2019	Medical Policy Implementation Committee approval. Added branded Luliconazole to the policy.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Added branded Sulconazole cream and solution as well as generic naftifine 1% gel to the policy.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Added products to the policy: naftifine 1% and naftifine 2% cream, Loprox 1% shampoo, Loprox 0.77% cream, Loprox 0.77% suspension, and oxiconazole 1% cream. Updated relevant portions of the policy to reflect the additions.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Added the generic equivalent of Kerydin, tavaborole 5% solution, to the policy.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Added the generic equivalent of Naftin 2% gel, naftifine 2% gel, to the policy.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2025

*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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.