



Louisiana

Topical Antifungals

Policy # 00527

Original Effective Date: 01/01/2017

Current Effective Date: 09/19/2018

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.*

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, Oxistat^{®±} 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, Ertaczo^{®±} 2% (sertaconazole) cream, Exelderm^{®±} 1% (sulconazole) cream, Exelderm 1% (sulconazole) solution, Naftin^{®±} 1% (naftifine) gel, Naftin 2% (naftifine) gel, Naftin 2% (naftifine) cream, Jublia^{®±} 10% (efinaconazole) solution, Kerydin^{®±} 5% (tavaborole) solution, Extina^{®±} 2% (ketoconazole) foam, and Xolegel^{®±} 2% (ketoconazole) gel 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, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, Exelderm 1% (sulconazole) solution, Naftin 1% (naftifine) gel, Naftin 2% (naftifine) gel, Naftin 2% (naftifine) cream, Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, Extina 2% (ketoconazole) foam, or Xolegel 2% (ketoconazole) gel when the following criteria are met for the requested drug:

- For Mentax 1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, Exelderm 1% (sulconazole) solution, Naftin 1% (naftifine) gel, Naftin 2% (naftifine) gel, or Naftin 2% (naftifine) cream requests:
 - o 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/was ineffective or will/did cause an adverse reaction to the patient.
- For Jublia 10% (efinaconazole) solution or Kerydin 5% (tavaborole) solution requests:
 - o 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/was ineffective or will/did cause an adverse reaction to the patient; AND
 - o 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

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that suggests the use of generically available topical ciclopirox will be/was ineffective or will/did cause an adverse reaction to the patient.

- For Xolegel 2% (ketoconazole) gel or Extina 2% (ketoconazole) foam requests:
 - o 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/was ineffective or will/did 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 Mentax1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, Exelderm 1% (sulconazole) solution, Naftin 1% (naftifine) gel, Naftin 2% (naftifine) gel, Naftin 2% (naftifine) cream, Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, Extina 2% (ketoconazole) foam, or Xolegel 2% (ketoconazole) gel 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/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary**.**

Schematic

Non-Preferred Products	Preferred Products
Mentax1% cream Ecoza 1% foam Luzu 1% cream Oxistat 1% lotion Oxistat 1% cream Ertaczo 2% cream Exelderm 1% cream Exelderm 1% solution Naftin 1% gel Naftin 2% gel Naftin 2% cream	Generic topical ketoconazole Generic topical clotrimazole Generic topical econazole
Jublia 10% solution Kerydin 5% solution	Generic oral terbinafine Generic oral itraconazole Generic topical ciclopirox solution
Xolegel 2% gel Extina 2% foam	Generic ketoconazole foam Generic ciclopirox gel/shampoo

Background/Overview

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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 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.

Rationale/Source

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 Mentax1% (butenafine) cream, Ecoza 1% (econazole) foam, Luzu 1% (luliconazole) cream, Oxistat 1% (oxiconazole) lotion, Oxistat 1% (oxiconazole) cream, Ertaczo 2% (sertaconazole) cream, Exelderm 1% (sulconazole) cream, Exelderm 1% (sulconazole) solution, Naftin 1% (naftifine) gel, Naftin 2% (naftifine) gel, Naftin 2% (naftifine) cream, Jublia 10% (efinaconazole) solution, Kerydin 5% (tavaborole) solution, Extina 2% (ketoconazole) foam, or Xolegel 2% (ketoconazole) gel 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 Pharmaceuticals. 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. Onychomycosis Management. UpToDate. Updated May 2016.
15. Seborrheic Dermatitis. UpToDate. Updated December 2015.
16. Extina [package insert]. Prestium Pharma. Newtown, Pennsylvania. Updated June 2013.

Policy History

Original Effective Date: 01/01/2017

Current Effective Date: 09/19/2018

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.

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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

Next Scheduled Review Date: 09/2019

****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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