Topical Antifungals

Policy # 00527
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017

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, branded Naftifine 1% cream, 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 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, branded Naftifine 1% cream, 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 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, branded Naftifine 1% cream, 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 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/was ineffective or will/did cause an adverse reaction to the patient

- For Jublia 10% (efinaconazole) solution or Kerydin 5% (tavaborole) 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/was ineffective or will/did cause an adverse reaction to the patient; AND
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- 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/was ineffective or will/did cause an adverse reaction to the patient

- For Xolegel 2% (ketoconazole) gel 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/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, branded Naftin1% cream, Naftin 1% (naftifine) gel, Naftin2% (naftifine) gel, Naftin 2% (naftifine) cream, Jubila 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

<table>
<thead>
<tr>
<th>Non-Preferred Products</th>
<th>Preferred Products</th>
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</thead>
<tbody>
<tr>
<td>Mentax1% cream</td>
<td>Generic topical ketoconazole</td>
</tr>
<tr>
<td>Ecoza 1% foam</td>
<td>Generic topical clotrimazole</td>
</tr>
<tr>
<td>Luzu 1% cream</td>
<td>Generic topical econazole</td>
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<tr>
<td>Oxistat 1% lotion</td>
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<td>Oxistat 1% cream</td>
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<td>Ertaczo 2% cream</td>
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<td>Naftin 2% cream</td>
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<td>Jubila 10% solution</td>
<td>Generic oral terbinafine</td>
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<tr>
<td>Kerydin 5% solution</td>
<td>Generic oral itraconazole</td>
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<tr>
<td>Xolegel 2% gel</td>
<td>Generic topical ciclopirox solution</td>
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<tr>
<td>Extina 2% foam</td>
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</tbody>
</table>

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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 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, branded Naftifine 1% cream, 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

Policy History
Original Effective Date: 01/01/2017
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09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 09/2017

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**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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