Pharmacy Medical Necessity Guidelines:
Immunomodulators, Topical

Effective: April 1, 2017

Prior Authorization Required ✓ Type of Review – Care Management
Not Covered Type of Review – Clinical Review ✓
Pharmacy (RX) or Medical (MED) Benefit RX Department to Review RXUM

This Pharmacy Medical Necessity Guidelines applies to the following:

Tufts Health Plan Commercial Plans
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617-673-0988

OVERVIEW

FDA-APPROVED INDICATIONS

Imiquimod is indicated for:
- Actinic keratosis (all strengths): For the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratoses on the full face or balding scalp in immunocompetent adults.
- Genital and perianal warts (3.75% and 5% cream only): For the treatment of external genital and perianal warts (condyloma acuminata) in patients 12 years and older.
- Superficial basal cell carcinoma (5% cream only): For the topical treatment of biopsy-confirmed, primary superficial basal cell carcinoma in immunocompetent adults with a maximum tumor diameter of 2 cm located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), when surgical methods are medically less appropriate and patient follow-up can be reasonably ensured

Ingenol is indicated for the topical treatment of actinic keratosis.

Pimecrolimus is indicated as second-line therapy for short-term and noncontinuous long-term treatment of mild to moderate atopic dermatitis in nonimmunocompromised patients 2 years and older who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

Tacrolimus ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

For actinic keratosis, imiquimod (Zyclara®) 2.5% and 3.75% treatment consists of up to 2 packets or pumps per day for two 14-day cycles separated by a 14-day rest period with no treatment; dosing should not exceed 56 packets or pumps per complete course of treatment (two 14-day cycles).

Fluorouracil 5% cream, imiquimod 5% cream and diclofenac 3% gel (Solaraze) are preferred products and are covered without prior authorization.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Preferred Drug List Status</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac 3% gel (generic Solaraze)</td>
<td>Tier 1</td>
<td>100gm per Rx; 90 days per year</td>
</tr>
<tr>
<td>Fluorouracil 0.5%, 5% cream (generic Carac, Efudex)</td>
<td>Tier 1</td>
<td>n/a</td>
</tr>
<tr>
<td>Medication</td>
<td>Preferred Drug List Status</td>
<td>Quantity Limit</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------</td>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Fluorouracil 2%, 5% solution</td>
<td>Tier 1</td>
<td>n/a</td>
</tr>
<tr>
<td>Imiquimod 5% cream (generic Aldara)</td>
<td>Tier 1</td>
<td>n/a</td>
</tr>
<tr>
<td>Imiquimod 2.5% and 3.75% (Zyclara)</td>
<td>PA; Tier 2</td>
<td>Two pumps or packets per day for up to two 14 day cycles</td>
</tr>
<tr>
<td>Ingenol 0.015%, 0.05% (Picato)</td>
<td>PA; Tier 2</td>
<td>One box per single treatment course</td>
</tr>
<tr>
<td>Pimecrolimus 1% (Elidel)</td>
<td>PA; Tier 2</td>
<td>100 gm per 30 days</td>
</tr>
<tr>
<td>Tacrolimus 0.03%, 0.1% (generic Protopic)</td>
<td>PA; Tier 1</td>
<td>One (30gm or 60gm) tube per Rx</td>
</tr>
</tbody>
</table>

**COVERAGE GUIDELINES**

The plan may authorize coverage of topical immunomodulators for Members when the following criteria for a particular regimen are met and limitations do not apply:

**Imiquimod 2.5% or 3.75% (Zyclara)**
1. The Member had an insufficient response to therapy, or the provider indicated clinical inappropriateness of therapy with the preferred products, imiquimod 5% and fluorouracil

**Ingenol (Picato)**
1. The Member had an insufficient response to therapy or the provider indicated clinical inappropriateness of therapy with the preferred product, fluorouracil

**Pimecrolimus or Tacrolimus**
1. The Member is at least 2 years of age
   AND
2. The request is for one of the following conditions:
   a) Atopic dermatitis (eczema)
   b) Lichen planus
   AND
3. The Member had an insufficient response to two topical anti-inflammatory agents of medium potency or greater, OR the Member is not a candidate for medium to high potency corticosteroid therapy (e.g., eyelid dermatitis or dermatitis associated with genital area eruptions)

<table>
<thead>
<tr>
<th>Low Potency</th>
<th>Medium Potency</th>
<th>High Potency</th>
<th>Very High Potency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alclometasone 0.05% Cream/Ointment</td>
<td>Betamethasone Valerate 0.1% Cream</td>
<td>Betamethasone Dipropionate 0.05% Cream/Ointment</td>
<td>Betamethasone Dip. Augmented 0.05% Ointment/Gel</td>
</tr>
<tr>
<td>Fluocinolone 0.01% Cream</td>
<td>Betamethasone Dipropionate 0.05% Lotion</td>
<td>Betamethasone Dip., Augmented 0.05% Cream</td>
<td></td>
</tr>
<tr>
<td>Hydrocortisone 0.5%, 1%, 2.5% Cream/Ointment/Lotion/Solution</td>
<td>Flucinolone 0.025% Cream/Ointment</td>
<td>Betamethasone Valerate 0.1% Ointment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluticasone 0.05% Cream/ointment</td>
<td>Desoximetasone 0.25% Cream/Ointment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocortisone Valerate 0.2% Cream</td>
<td>Fluocinonide 0.05% Cream/Ointment/Gel/Soln</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mometasone 0.1% Cream/Oint/Soln</td>
<td>Triamcinolone 0.5% Cream/Ointment</td>
<td></td>
</tr>
</tbody>
</table>
### Non-Preferred Products

<table>
<thead>
<tr>
<th>Low Potency</th>
<th>Medium Potency</th>
<th>High Potency</th>
<th>Very High Potency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Triamcinolone</strong> 0.025%, 0.1% Cream/Ointment/Lotion</td>
<td></td>
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<td></td>
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<tr>
<td>Desonide 0.05% Cream/Lotion/Ointment</td>
<td>Flurandrenolide 0.025%, 0.05% Cream/Oint; 4 mcg/cm² tape</td>
<td>Aminiconde 0.01% Cream/Lotion/Ointment</td>
<td>Clobetasol 0.05% Cream/Ointment/Gel/Solution</td>
</tr>
<tr>
<td>Clocortolone 0.1% Cream</td>
<td>Desoximetasone 0.05% Gel</td>
<td>Diflorasone 0.05% Ointment</td>
<td></td>
</tr>
<tr>
<td>Desoximetasone 0.05% Cream/Ointment</td>
<td>Diflorasone 0.05% Cream</td>
<td>Flucinonide 0.1% Cream</td>
<td></td>
</tr>
<tr>
<td>Hydrocortisone Butyrate Cream/Ointment/Solution</td>
<td>Halcinonide 0.1% Cream/Ointment</td>
<td>Halobetasol 0.05% Cream/Ointment</td>
<td></td>
</tr>
<tr>
<td>Hydrocortisone Valerate 0.2% Ointment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
2. Approval of tacrolimus ointment for Members 2 to 15 years of age will be limited to the 0.03% strength.

### CODES

None

### REFERENCES

9. PR Newswire. FDA Approves Picato® (ingenol mebutate) Gel, the First and Only Topical Actinic Keratosis (AK) Therapy With 2 or 3 Consecutive Days of Once-Daily Dosing Source: http://s.tt/1bEB6.

### APPROVAL HISTORY

December 9, 2014: Reviewed by Pharmacy & Therapeutics Committee. Consolidation of criteria for individual products; approval duration limited to one year for tacrolimus and pimecrolimus.

Subsequent endorsement date(s) and changes made:
November 10, 2015: Incorporated a table to include the topical immunomodulator medications and their coverage status; no change in clinical content.

January 1, 2016: Administrative change to rebranded template.

November 15, 2016: Removed vitiligo in a sun-exposed area of the skin as an approvable diagnosis for pimecrolimus or tacrolimus. Removed "requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria".

April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services