### PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>ACTINIC KERATOSIS PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAND NAME*</td>
<td>(generic)</td>
</tr>
<tr>
<td></td>
<td>CARAC (fluorouracil)</td>
</tr>
<tr>
<td></td>
<td>FLUOROPLEX (fluorouracil)</td>
</tr>
<tr>
<td></td>
<td>PICATO (ingenol mebutate)</td>
</tr>
<tr>
<td></td>
<td>TOLAK (fluorouracil)</td>
</tr>
<tr>
<td></td>
<td>ZYCLARA (imiquimod)</td>
</tr>
</tbody>
</table>

**Status:** CVS Caremark Criteria  
**Type:** Initial Prior Authorization  
**Ref # 1378-A**

*Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

### FDA-APPROVED INDICATIONS

**Carac**  
Carac is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

**Fluoroplex**  
Fluoroplex cream is indicated for the topical treatment of multiple actinic (solar) keratoses.

**Picato**  
Picato gel is indicated for the topical treatment of actinic keratosis.

**Tolak**  
Tolak (fluorouracil) cream is indicated for the topical treatment of actinic keratosis lesions of the face, ears and/or scalp.

**Zyclara**  
**Actinic Keratosis**  
Zyclara Cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical visible or palpable, actinic keratoses (AK), of the full face or balding scalp in immunocompetent adults.

**External Genital Warts**  
Zyclara Cream, 3.75% is indicated for the treatment of external genital and perianal warts (EGW)/condyloma acuminata in patients 12 years or older.
COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has the diagnosis of actinic keratosis
  OR
- The patient has the diagnosis of external genital warts AND the request is for Zyclara

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Carac is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp. Fluoroplex cream is indicated for is indicated for the topical treatment of multiple actinic (solar) keratoses. Tolak cream is indicated for the topical treatment of actinic keratosis lesions of the face, ears and/or scalp. Picato gel is indicated for the topical treatment of actinic keratosis. Zyclara cream is indicated for the topical treatment of clinically typical visible or palpable, actinic keratoses (AK), of the full face or balding scalp in immunocompetent adults and for the treatment of external genital and perianal warts (EGW)/condyloma acuminata in patients 12 years or older.

REFERENCES

CRITERIA FOR APPROVAL

<table>
<thead>
<tr>
<th>Mapping Instructions</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Approve, 12 months</td>
<td>Go to 2</td>
<td>Deny</td>
</tr>
<tr>
<td>2. Go to 3</td>
<td>Deny</td>
<td>You do not meet the requirements of your plan. Your plan covers this drug when you have any of the following conditions:</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>3.</th>
<th>Approve, 12 months</th>
<th>Deny</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>You do not meet the requirements of your plan. Your plan covers this drug when you have actinic keratosis. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis for Carac, Fluoroplex, Picato, Tolak]</td>
</tr>
</tbody>
</table>