## PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>BRAND NAME* (generic)</th>
<th>CARAC (fluorouracil)</th>
<th>FLUOROPLEX (fluorouracil)</th>
<th>PICATO (ingenol mebutate)</th>
<th>TOLAK (fluorouracil)</th>
<th>ZYCLARA (imiquimod)</th>
</tr>
</thead>
</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 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 external genital warts
RATIONALE
These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

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 lesions of the face, ears and/or scalp. Picato gel is indicated for the topical treatment of actinic keratosis. Zyclara cream is indicated for actinic keratosis and external genital warts.

REFERENCES

CRITERIA FOR APPROVAL

<table>
<thead>
<tr>
<th>Duration of Approval</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set 1</td>
<td></td>
</tr>
<tr>
<td>Yes to question(s)</td>
<td>No to question(s)</td>
</tr>
<tr>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

Mapping Instructions

<table>
<thead>
<tr>
<th>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Approve, 12 months Deny You do not meet the requirements of your plan. Your plan covers this drug when you have actinic keratosis or external genital warts. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]</td>
</tr>
</tbody>
</table>