

**Actinic Keratosis Products**  
**Carac (fluorouracil), Fluoroplex (fluorouracil),**  
**Picato (ingenol mebutate), Tolak (fluorouracil),**  
**Zyclara (imiquimod)**  
**Effective 01/01/2024**

|                              |   |                     |   |
|------------------------------|---|---------------------|---|
| <b>Plan</b>                  | <input type="checkbox"/> MassHealth UPPL<br><input checked="" type="checkbox"/> Commercial/Exchange | <b>Program Type</b> | <input checked="" type="checkbox"/> Prior Authorization<br><input type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input type="checkbox"/> Medical Benefit    |                     |   |
| <b>Specialty Limitations</b> | N/A   |                     |   |
| <b>Contact Information</b>   | <b>Medical and Specialty Medications</b>  |                     |   |
|                              | All Plans   | Phone: 877-519-1908 | Fax: 855-540-3693   |
| <b>Exceptions</b>            | <b>Non-Specialty Medications</b>  |                     |   |
|                              | All Plans   | Phone: 800-711-4555 | Fax: 844-403-1029   |

### Overview

#### 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**

- 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
- 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 Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted when the following criteria is met:

1. Member has a diagnosis of actinic keratosis
2. For Zyclara, member has a diagnosis of external genital warts

**Limitations**

1. Initial approvals will be granted for 12 months.

**References**

1. Carac [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America; May 2017.
2. Fluoroplex [package insert]. West Chester, PA: Aqua Pharmaceuticals; July 2016.
3. Picato [package insert]. Parsippany, NJ: LEO Pharma; February 2020.
4. Tolak [package insert]. Parsippany, NJ: Pierre Fabre Pharmaceuticals; Inc. March 2017.
5. Zyclara [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2018.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed June 2020.
7. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 2020.

**Review History**

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

