

PRIOR AUTHORIZATION CRITERIA

BRAND NAME* (generic)

CARAC
(fluorouracil)

FLUOROPLEX
(fluorouracil)

PICATO
(ingenol mebutate)

TOLAK
(fluorouracil)

ZYCLARA
(imiquimod)

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. 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 actinic keratosis and external genital warts.

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; June 2017.
4. Tolak [package insert]. Sanford, FL: Hill Dermaceuticals; Inc. March 2017.
5. Zyclara [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2017.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed June 2019.
7. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 2019.

Date Written: 06/2016
Revised: (SF) 08/2016 (added target drugs); 06/2017 (no clinical changes), (ME) 06/2018 (no clinical changes), 06/2019 (Removed MDC from Title)
Reviewed: Medical Affairs (MM) 06/2016
External Review: 08/2016, 10/2017, 10/2018, 08/2019

CRITERIA FOR APPROVAL

1	Does the patient have the diagnosis of actinic keratosis or external genital warts?	Yes	No
---	---	-----	----

Guidelines for Approval

Duration of Approval		12 Months
Set 1		
Yes to question(s)	No to question(s)	
1	None	

Mapping Instructions

	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
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]