PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ACTINIC KERATOSIS PRODUCTS**
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 (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.

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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

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.

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); (RP) 06/2020
Reviewed: Medical Affairs (MM) 06/2016; (CHART) 06/25/2020
External Review: 08/2016, 10/2017, 10/2018, 08/2019, 08/2020

CRITERIA FOR APPROVAL

1	Does the patient have the diagnosis of actinic keratosis? [If yes, then no further questions.]	Yes	No
2	Does the patient have the diagnosis of external genital warts? [If no, then no further questions.]	Yes	No
3	Is the request for Zyclara?	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 12 months	Go to 2	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have any of the following conditions:

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			- Actinic keratosis - External genital warts and the drug being requested is Zyclara Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
3.	Approve, 12 months	Deny	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]

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