Reference number(s)
1378-A

Initial Prior Authorization
Actinic Keratosis Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Carac	fluorouracil	all
Fluoroplex	fluorouracil	all
Tolak	fluorouracil	all
Zyclara	imiquimod	all

Indications

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.

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.

Limitations of Use

Imiquimod cream has been evaluated in children ages 2 to 12 years with molluscum contagiosum and these studies failed to demonstrate efficacy.

Treatment with Zyclara Cream has not been studied for prevention or transmission of human papillomavirus (HPV).

Coverage Criteria

Actinic Keratosis (AK)

Authorization may be granted when the patient has the diagnosis of actinic keratosis (AK).

External Genital Warts

Authorization may be granted when the patient has the diagnosis of external genital warts when the following criteria is met:

- The request is for Zyclara

Continuation of Therapy

Actinic Keratosis (AK)

Authorization may be granted when the patient has the diagnosis of actinic keratosis (AK) when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of actinic keratosis lesions cleared, patient/prescriber satisfaction, etc.)

External Genital Warts

Authorization may be granted when the patient has the diagnosis of external genital warts when ALL of the following criteria is met:

- The request is for Zyclara
- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of warts cleared)

Duration of Approval (DOA)

- 1378-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

1. Carac [package insert]. Bridgewater, NJ: Bausch Health US, LLC; May 2021.
2. Fluoroplex [package insert]. Exton, PA: Almirall, LLC; February 2022.
3. Tolak [package insert]. Sanford, FL: Hill Dermaceuticals, Inc. August 2022.
4. Zyclara [package insert]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 15, 2023.
6. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/12/2023).
7. Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021;85:e209-e233.
8. Steeb T, Wessely A, Petzold A, et al. How to Assess the Efficacy of Interventions for Actinic Keratosis? A Review with a Focus on Long-Term Results. J Clin Med. 2021 Oct 15;10(20):4736.