BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

CARAC® (fluorouracil) cream 0.5%
FLUOROURACIL cream 0.5%

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for: CARAC (fluorouracil) cream 0.5% and FLUOROURACIL cream 0.5% generic

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Dermatologist or in consultation with a Dermatologist

Indication
- Multiple actinic or solar keratoses of the face and scalp

ORIGINAL EFFECTIVE DATE: 03/15/2018 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/19/2026

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Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Has five or more actinic keratoses (AKs) or solar keratoses on the face or anterior bald scalp

Alternative Therapies
- Failure (trial for at least three months duration), contraindication per Food and Drug Administration (FDA) label, intolerance, or not a candidate for **BOTH** of the following:
  - Generic fluorouracil solution (2 percent or 5 percent)
  - Generic imiquimod 5 percent cream

Brand Specific Criteria
- Failure (trial of at least three months duration), contraindication per Food and Drug Administration (FDA) label, intolerance, or not a candidate for **generic fluorouracil 0.5 percent cream**. **Note:** Failure, contraindication, or intolerance to the generic should be reported to the FDA (see Definitions section)

Safety
- Does not have any of the following:
  - Hypersensitivity to fluorouracil or any component of the formulation
  - Dihydropyrimidine dehydrogenase (DPD) enzyme deficiency
  - Pregnancy or potential for pregnancy during therapy

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 3 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by a Dermatologist or is in consultation with a Dermatologist

Clinical Response
- At least seventy five percent of treated lesions have cleared

Adherence
- Adherence to the prescribed therapy regimen has been documented

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Brand Specific Criteria

- **For brand Carac (fluorouracil) 0.5 percent cream:** Failure (trial of at least three months duration), contraindication per Food and Drug Administration (FDA) label, intolerance, or not a candidate for **generic fluorouracil 0.5 percent cream**. **Note:** Failure, contraindication, or intolerance to the generic should be reported to the FDA (see Definitions section)

Safety

- Does not have any of the following:
  - Hypersensitivity to fluorouracil or any component of the formulation
  - Dihydropyrimidine dehydrogenase (DPD) enzyme deficiency
  - Pregnancy or potential for pregnancy during therapy
  - Bloody diarrhea
  - Stomatitis
  - Severe abdominal pain
  - Vomiting

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in actinic keratosis
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration

- 3 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Carac (fluorouracil) 0.5% cream is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

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Resources:

Carac (fluorouracil) 0.5% cream product information, revised by Bausch Health US, LLC. 05-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 30, 2025.

Fluorouracil 0.5% cream product information, revised by Mylan Pharmaceuticals, Inc. 01-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 21, 2024. **Discontinued 09-24-2024**.

Berman B. Treatment of actinic keratosis. In: UpToDate, Dellavalle RP, Robinson JK, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through December 2025. Topic last updated April 02, 2025. Accessed January 03, 2026.