

## 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 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](http://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](mailto:Pharmacyprecert@azblue.com).

#### Criteria:

- **Criteria for initial therapy:** Carac (fluorouracil) 0.5% cream and fluorouracil 0.5% cream is considered **medically necessary** and will be approved when **ALL** the following criteria are met:
1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with a Dermatologist
  2. Individual is 18 years of age or older
  3. Individual has a confirmed diagnosis of multiple actinic or solar keratoses of the face and scalp
  4. **For Actinic keratosis:** Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for generic fluorouracil 2% or 5% solution or generic imiquimod 5% cream

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5. **For brand Carac (fluorouracil) 0.5% cream:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic fluorouracil 0.5% cream** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
6. There are **NO** FDA-label contraindications such as:
  - a. Hypersensitivity to fluorouracil or any component of the formulation
  - b. Dihydropyrimidine dehydrogenase (DPD) enzyme deficiency
  - c. Woman who is or may become pregnant during therapy

**Initial approval duration:** 3 months

- **Criteria for continuation of coverage (renewal request):** Carac (fluorouracil) 0.5% cream and fluorouracil 0.5% cream is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
  2. The indication for use is one that requires a longer duration as patient has not reached the erosion stage or additional dosage due to high number of lesions
  3. 1-2 months have passed since the last treatment with fluorouracil therapy as complete healing takes that much time
  4. **For Actinic keratosis, request for brand Carac or fluorouracil 0.5% cream:** Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for generic fluorouracil 2% or 5% solution or generic imiquimod 5% cream
  5. **For brand Carac (fluorouracil) 0.5% cream:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic fluorouracil 0.5% cream** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
  6. Individual has been adherent with the medication
  7. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follows:
    - a. Contraindications as listed in the criteria for initial therapy section
    - b. Bloody diarrhea, stomatitis, severe abdominal pain, vomiting etc. indicating dihydropyrimidine dehydrogenase deficiency (DPD) enzyme deficiency

**Renewal duration:** 3 months

- 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

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#### 2. Off-Label Use of Cancer Medications

##### **Description:**

Fluorouracil is indicated for the management of multiple actinic or solar keratoses. Fluorouracil (5% strength) is also indicated for the treatment of superficial basal cell carcinoma when conventional methods are impractical (e.g., due to multiple lesions or difficult treatment sites).

It is important to establish diagnosis of superficial basal cell carcinoma prior to treatment as fluorouracil has not been proven effective in other types of basal cell carcinomas. Surgery is preferred with isolated, easily accessible basal cell carcinomas because success with such lesions is almost 100% and the success rate with fluorouracil cream and solution is approximately 93%.

##### **Definitions:**

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

##### **Features that identify basal cell carcinomas (BCCs) with a low likelihood for recurrence after treatment:**

- Location and size:
  - < 2 cm in diameter on trunk and extremities, excluding genitalia, pretibia, hands, feet, cheeks, forehead, scalp, and neck
- Pathology:
  - Nodular or superficial histopathologic growth pattern, other nonaggressive growth patterns (infundibulocystic, fibroepithelioma of Pinkus)
  - Lack of perineural invasion
- Other:
  - Primary lesion (not recurrent)
  - Well-defined clinical borders
  - No history of radiation therapy at site
  - Immunocompetent individual

##### **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 November 21, 2024.

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.

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 November 2024. Topic last updated July 10, 2024. Accessed December 27, 2024.

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### **CARAC® (fluorouracil) cream 0.5%** **Fluorouracil cream 0.5%**

Aasi SZ. Treatment and prognosis of basal cell carcinoma at low risk for recurrence. In: UpToDate, Stern RS, Robinson JK, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Literature current through November 2024. Topic last updated October 11, 2024. Accessed December 27, 2024.

Aasi SZ, Hong AM. Treatment of basal cell carcinoma at high risk for recurrence. In: UpToDate, Robinson JK, Stern RS, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Literature current through November 2024. Topic last updated May 07, 2024. Accessed December 27, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Basal Cell Skin Cancer Version 3.2024 – Updated March 01, 2024. Available at <https://www.nccn.org>. Accessed December 27, 2024

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