



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/15/2018  
LAST REVIEW DATE: 2/17/2022  
LAST CRITERIA REVISION DATE: 2/17/2022  
ARCHIVE DATE:

---

**CARAC® (fluorouracil) cream 0.5%**  
**EFUDEX® (fluorouracil) cream 5%**  
**FLUOROPLEX® (fluorouracil) cream 1%**  
**Fluorouracil cream 0.5%**

---

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

**BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.**

---

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/15/2018  
LAST REVIEW DATE: 2/17/2022  
LAST CRITERIA REVISION DATE: 2/17/2022  
ARCHIVE DATE:

---

**CARAC® (fluorouracil) cream 0.5%**  
**EFUDEX® (fluorouracil) cream 5%**  
**FLUOROPLEX® (fluorouracil) cream 1%**  
**Fluorouracil cream 0.5%**

---

864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

---

**Criteria:**

- **Criteria for initial therapy:** Carac (fluorouracil) 0.5% cream and Fluorouracil 0.5% cream, Efudex (fluorouracil) 5% cream, and Fluoroplex (fluorouracil) 1% cream is considered **medically necessary** and will be approved when **ALL** of 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. A confirmed diagnosis of **ONE** of the following:
    - a. Multiple actinic (solar) keratoses
    - b. **For Efudex 5% cream:** Superficial basal cell carcinomas when conventional methods are impractical (e.g., multiple lesions or difficult treatment sites)
  4. **ONE** of the following:
    - a. **For Actinic keratosis:** Individual has failure, contraindication per FDA label, or intolerance to **BOTH** Tolak (fluorouracil) 4% cream and 2% fluorouracil solution
    - b. **For Superficial basal cell carcinomas:** Individual has failure, contraindication per FDA label, or intolerance to generic fluorouracil cream 5%
  5. 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. Women who are or may become pregnant

**Initial approval duration:** 2 months

- **Criteria for continuation of coverage (renewal request):** Carac (fluorouracil) 0.5% cream and Fluorouracil 0.5% cream, Efudex (fluorouracil) 5% cream, and Fluoroplex (fluorouracil) 1% cream is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/15/2018  
LAST REVIEW DATE: 2/17/2022  
LAST CRITERIA REVISION DATE: 2/17/2022  
ARCHIVE DATE:

---

**CARAC® (fluorouracil) cream 0.5%**  
**EFUDEX® (fluorouracil) cream 5%**  
**FLUOROPLEX® (fluorouracil) cream 1%**  
**Fluorouracil cream 0.5%**

---

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 has passed since the last treatment with fluorouracil therapy as complete healing takes that much time
4. Individual has been adherent with the medication
5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
  - a. Contraindications as listed in the criteria for initial therapy section
  - b. Significant adverse effect such as:
    - i. Bloody diarrhea, stomatitis, severe abdominal pain, vomiting etc. indicating dihydropyrimidine dehydrogenase deficiency (DPD) enzyme deficiency
6. There are no significant interacting drugs

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

---

**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 December 28, 2021.

Fluorouracil 0.5% cream product information, revised by Mylan Pharmaceuticals, Inc. 01-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 28, 2021.

Efudex (fluorouracil) 5% cream and 2% and 5 % solution product information, revised by Bausch Health US, LLC. 10-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 28, 2021.

Fluorouracil 5% cream product information, revised by Mylan Pharmaceuticals, Inc. 06-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 28, 2021.



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/15/2018  
LAST REVIEW DATE: 2/17/2022  
LAST CRITERIA REVISION DATE: 2/17/2022  
ARCHIVE DATE:

---

**CARAC® (fluorouracil) cream 0.5%**  
**EFUDEX® (fluorouracil) cream 5%**  
**FLUOROPLEX® (fluorouracil) cream 1%**  
**Fluorouracil cream 0.5%**

---

Fluorouracil 2% and 5 % solution product information, revised by Taro Pharmaceuticals U.S.A., Inc. 10-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 28, 2021.

Tolak (fluorouracil) 4% cream product information, revised by Hill Dermaceuticals, Inc. 09-2015. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 28, 2021.

Fluoroplex (fluorouracil) 1% cream product information, revised by Almirall, LLC 04-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 28, 2021.

Berman B. Treatment of actinic keratosis. In: UpToDate, Dellavalle RP, Robinson JK, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Topic last updated July 13, 2021. Accessed December 28, 2021.