Pharmacy Policy Bulletin: J-0545 Diclofenac sodium 3% gel and Carac (fluorouracil 0.5%) cream - Commercial and Healthcare Reform	
Number: J-0545	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0545-010	**Original Date:** 05/24/2017
Effective Date: 02/14/2025	**Review Date:** 01/29/2025

Drugs Product(s):	• Diclofenac sodium 3% topical gel • Carac (fluorouracil) 0.5% topical cream • fluorouracil 0.5% topical cream

FDA-Approved Indication(s):	• Diclofenac sodium 3% topical gel
	  ○ Topical treatment of actinic keratosis (AK)
	• Carac 0.5%, fluorouracil 0.5% topical cream
	  ○ Topical treatment of multiple actinic or solar keratoses of the face and anterior scalp

Background:	• The mechanism of action of diclofenac sodium, a nonsteroidal anti-inflammatory drug (NSAID), in the treatment of actinic keratosis (AK) is unknown. • Fluorouracil (FU), an antimetabolite, may create a thymine deficiency that provokes unbalanced growth and death of the cell. • Actinic keratosis is a cutaneous lesion that can occasionally progress to skin cell carcinoma. Sun exposure is one of the major risk factors for the development of actinic keratosis. Actinic keratosis is more likely to affect males with fair skin. The prevalence of actinic keratosis increases with age. • The 2021 American Academy of Dermatology (AAD) guidelines strongly recommend topical fluorouracil or topical imiquimod for the treatment of AK. Conditional recommendations were made for the use of photodynamic therapy (PDT) or topical diclofenac 3% for the treatment of AK, both individually and as part of combination therapy regimens. Field-directed therapies, such as topical fluorouracil, topical imiquimod, and photodynamic therapy (PDT), are particularly useful for treating areas with multiple AK lesions. • Prior authorization is utilized to ensure appropriate use. Step therapy contains criteria for prior utilization of products that are guideline recommended, equally or more efficacious, and less costly. • Prescribing Considerations: ○ NSAIDs can cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal.

	○ Diclofenac sodium 3% is contraindicated in patients with a known hypersensitivity to diclofenac, or any components of the drug product; in the setting of coronary artery bypass graft (CABG) surgery; history of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs; use on damaged skin. ○ Carac is contraindicated in pregnancy and in patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency. ○ The recommended duration of therapy for diclofenac sodium 3% gel is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be re-evaluated and management reconsidered. ○ The recommended duration of therapy for Carac is up to 4 weeks as tolerated. ○ Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using diclofenac sodium 3%. Advise patients to discontinue treatment with diclofenac sodium 3% at the first evidence of sunburn.

Approval Criteria

I. Diclofenac sodium 3%

A. Initial Authorization

When a benefit, coverage of diclofenac sodium 3% may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of actinic keratosis (ICD-10: L57.0).
3. The member has experienced therapeutic failure or intolerance to one (1) of the following generic topical products, or contraindication to all **(a. or b.)**:
   - **a.** fluorouracil solution
   - **b.** fluorouracil 5% cream
4. The member has experienced therapeutic failure or intolerance to plan-preferred generic imiquimod 5% topical cream.

B. Reauthorization

When a benefit, reauthorization of diclofenac sodium 3% may be approved when all of the following criteria are met **(1. and 2.)**:

1. The prescriber attests that the member previously responded to diclofenac sodium 3% topical gel therapy.
2. The prescriber attests the member is re-starting therapy at least 30 days after cessation of diclofenac sodium 3% topical gel therapy.

II. Carac 0.5%, fluorouracil 0.5%

A. Initial Authorization

When a benefit, coverage of Carac 0.5% or fluorouracil 0.5% may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 18 years of age or older
2. The member has a diagnosis of multiple actinic keratoses (solar keratoses) (ICD-10 L57.0) of the face or anterior scalp.
3. The member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred generic topical products **(a. or b.)**:

a. fluorouracil solution
b. fluorouracil 5% cream

4. The member has experienced therapeutic failure or intolerance to plan-preferred generic imiquimod 5% topical cream.
5. If the request is for brand Carac, the member has experienced therapeutic failure or intolerance to fluorouracil 0.5% topical cream.

B. Reauthorization
When a benefit, reauthorization of Carac 0.5% or fluorouracil 0.5% may be approved when all of the following criteria are met **(1., 2., and 3.)**:
1. The prescriber attests that the member previously responded to Carac 0.5% or fluorouracil 0.5% topical therapy.
2. The prescriber attests that the member is experiencing recurrence of actinic keratosis.
3. If the request is for brand Carac, the member has experienced therapeutic failure or intolerance to fluorouracil 0.5% topical cream.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans:
  - Diclofenac sodium 3% gel: If approved, up to a 3 month authorization may be granted.
  - Carac 0.5% or fluorouracil 0.5% cream: If approved, up to a 1 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Diclofenac sodium topical gel 3% [package insert]. Mahwah, NJ: Glenmark Pharmaceuticals Inc., USA; July 2024.
2. Carac cream [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; May 2022.
3. Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. *J Am Acad Dermatol.* 2021;85(4):e209-233.