FLUOROURACIL 0.5% CREAM

Generic	Brand	HICL	GCN	Exception/Other
FLUOROURACIL 0.5%	CARAC		12514	

This drug requires a written request for prior authorization.

GUIDELINE FOR USE

1. Does the patient have a diagnosis of actinic or solar keratosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a previous trial of at least **ONE** of the following?
   - Generic topical agents (e.g., imiquimod 5%, diclofenac 3%, fluorouracil 5%)
   - Preferred topical agents (e.g., Picato)

   If yes, **approve fluorouracil 0.5% for 1 month by GPID 12514 with no quantity limit.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **FLUOROURACIL 0.5% CREAM (Carac)** requires a diagnosis of actinic or solar keratosis. In addition, the following criterion must be met:
   - The patient has received a trial of **ONE** of the following:
     - Generic topical agents (e.g., imiquimod 5%, diclofenac 3%, fluorouracil 5%)
     - Preferred topical agents (e.g., Picato)

RATIONALE
To ensure appropriate utilization of topical fluorouracil 0.5% cream based on approved FDA indications and dosing.

FDA APPROVED INDICATIONS
Fluorouracil is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

DOSAGE AND ADMINISTRATION
Fluorouracil cream should be applied once a day to the skin where actinic or solar keratosis lesions appear, using enough to cover the entire area with a thin film. Fluorouracil cream should not be applied near the eyes, nostrils, or mouth. It should be applied 10 minutes after thoroughly washing, rinsing, and drying the entire area. It may be applied using the fingertips. Immediately after application,
the hands should be thoroughly washed. Fluorouracil cream should be applied up to 4 weeks as tolerated.

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FLUOROURACIL 0.5% CREAM

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION
Continued treatment up to 4 weeks results in greater lesion reduction. Local irritation is not markedly increased by extending treatment from 2 to 4 weeks, and is generally resolved within 2 weeks of cessation of treatment.

REFERENCES

- Carac [Prescribing Information]. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. May 2017.
- Werner RN, Stockfleth E, Connolly SM, et al. Evidence-and consensus-based (S3) Guidelines for the Treatment of Actinic Keratosis – International League of Dermatological Societies in cooperation with the European Dermatology Forum – Short version. *JEADV.* 2015; 29:2069-2079.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/18
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P&T Approval: 07/18