HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

ACTINIC KERATOSIS AGENTS

Generic	Brand	HICL	GCN	Exception/Other
DICLOFENAC SODIUM	DICLOFENAC SODIUM. SOLARAZE		86831	
FLUOROURACIL	FLUOROPLEX		30780	
FLUOROURACIL	FLUOROURACIL, CARAC		12514	
INGENOL MEBUTATE	PICATO	38449		

NOTE: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at point of service with a message indicating that prior authorization (PA) is required.

Members who do not meet the step therapy criteria at point of service will need to submit a Medication Request Form (MRF) to MedImpact for clinical review. First level drug therapy required include the following:

- Actinic Keratosis: generic fluorouracil 5% cream/solution, fluorouracil 2% solution or imiquimod 5% cream
- Condyloma acuminata: imiquimod 5% cream
- Lookback is 180 days,
- Lookback will also include brand name agents and look for itself.

GUIDELINES FOR USE

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

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient tried and failed therapy with fluorouracil 5% cream/solution, fluorouracil 2% solution, or imiquimod 5% cream?

   If yes, continue to #5.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Actinic Keratosis Agents guideline, this medication is only covered for members with actinic keratosis when they have tried and failed therapy with fluorouracil 5% cream/solution, fluorouracil 2% solution, or imiquimod 5% cream. Your provider did not indicate that you have tried and failed therapy with any of the previously listed medications and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of condyloma acuminata?

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Actinic Keratosis Agents guideline, this medication is only covered for members with actinic keratosis or condyloma acuminata. Your provider did not indicate that you have actinic keratosis or condyloma acuminata and therefore your request was not approved.

4. Has the patient tried and failed therapy with imiquimod 5% cream?

   If yes, continue to #5.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Actinic Keratosis Agents guideline, this medication is only covered for members with condyloma acuminata when they have tried and failed therapy with imiquimod 5% cream. Your provider did not indicate that you have tried and failed therapy with imiquimod 5% cream and therefore your request was not approved.

5. Is this request for a multisource brand, such as Efudex, Solaraze or Carac?

   If yes, continue to #6.
   If no, continue to #7.

6. Has the patient tried and failed therapy with the generic equivalent of the multisource brand name product?

   If yes, continue to #7.
   If no, do not approve. Please enter a proactive PA for the generic version of the requested product for 4 months. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Actinic Keratosis Agents guideline, this medication is only covered after you have tried and failed therapy with the generic equivalent of the requested medication. Your provider did not indicate that you have tried and failed the generic equivalent and therefore your request was not approved. You have been approved for **[Generic equivalent]** for a 4-month period.

7. **Please approve for 4 months by GPID**. Please use status code #057 and the approval text provided.
   APPROVAL TEXT: Your request for _____ has been approved for a 4-month period.

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RATIONALE

To promote the first line use of generic equivalents of brand medications for the treatment of actinic keratosis and condyloma accuminata.

An approval duration of 4 months provides adequate coverage for a repeat course of therapy in patients with multiple actinic keratosis lesions.

FDA APPROVED INDICATIONS

Diclofenac 3% is a topical treatment containing a non-steroidal anti-inflammatory drug for the management of actinic keratoses.

Fluoroplex (fluorouracil 1%) is an antineoplastic/antimetabolite cream indicated for topical treatment of multiple actinic (solar) keratoses.

Fluorouracil 0.5% is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

Fluorouracil 5% cream or solution is indicated for the treatment of superficial basal cell carcinoma when conventional methods are impractical. Treatment may be continued for up to 12 weeks for superficial basal cell carcinomas.

Imiquimod is indicated for:

- The topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratoses on the full face or balding scalp in immunocompetent adults; (all strengths).
- The treatment of external genital and perianal warts (condyloma acuminata) in patients 12 years and older; (3.75% and 5% cream only).
- The topical treatment of biopsy-confirmed, primary superficial basal cell carcinoma in immunocompetent adults with a maximum tumor diameter of 2 cm located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably ensured; (5% cream only).

Treatment with imiquimod 5% cream should continue until there is total clearance of the genital/perianal warts or a maximum duration of therapy of 16 weeks. Patients with multiple actinic keratosis may be treatment with imiquimod 5% cream for 16 weeks.

Picato (ingenol mebutate) gel is indicated for the topical treatment of actinic keratosis for up to three consecutive days.

REFERENCES

- Aqua Pharmaceuticals. Fluoroplex package insert. West Chester, PA 19380. March 2012.
- Valeant Pharmaceuticals. Carac package insert. Bridgewater, NJ. 08807. November 2015.
- CSL Limited. Solaraze package insert. Parkville, VIC. 3052. December 2008.
- LEO Pharma Inc. Picato package insert. Parsippany, NJ. 07054. September 2015.Facts & Comparisons 4.0 [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2010. Available at: http://online.factsandcomparisons.com/index.aspx. [Accessed: October 6, 2016].
- Jorizzo J. Treatment of Actinic Keratosis. In: UpToDate, Corner R (ed), Wlatham, MA, December 2016.