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.

NOTE: To determine if a member is on a closed formulary, check the benefit description associated with the benefit code, if the word 'CLOSED' is in the benefit description then is a closed benefit.

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 following denial language: **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 physician did not indicate that you have tried and failed therapy with any of the previously listed medications and therefore your request was not approved.

CONTINUED ON NEXT PAGE
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 following denial language:
   **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 physician 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 following denial language:
   **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 physician 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 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 product for 4 months. Please use status code #238 and the following denial language:
   **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. [Generic equivalent] has been approved for your use for a 4-month period. Your physician did not indicate that you have tried and failed the generic equivalent and therefore your request was not approved.

7. **Please approve for 4 months by GPID.** Please use status code #057 and the following approval language:

   **APPROVAL TEXT:** Your request for __________ has been approved for a 4 month period.

   **CONTINUED ON NEXT PAGE**
RATIONAL
To allow for appropriate utilization based on FDA approved indication following trial of imiquimod cream or generically available topical fluorouracil.

Approval duration of 4 months provides adequate coverage for a repeat course of therapy, when a patient present 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 keratoses may be treated with imiquimod 5% cream for 16 weeks.

Picato (ingenol mebutate) gel is indicated for the topical treatment of actinic keratosis.

REFERENCES