Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number: PA.CP.PMN.165	**Effective Date: 01/2020** **Revision Date: 10/2021**
Policy Name: Fluorouracil Cream (Tolak)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Fluorouracil Cream (Tolak)

Reference Number: PA.CP.PMN.165
Effective Date: 10.17.18
Last Review Date: 10/2021

Revision Log

Description
Fluorouracil (Tolak® Cream, 4%) is a nucleoside metabolic inhibitor.

FDA Approved Indication(s)
Tolak is indicated for the topical treatment of actinic keratosis lesions of the face, ears, and scalp.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Tolak is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Actinic Keratosis (must meet all)**:**

1. Diagnosis of actinic ketatosis lesions on the face, ears and/or scalp;
2. Failure of topical fluorouracil 5% topical cream, unless contraindicated or clinically significant adverse effects are experienced.
3. Dose does not exceed once daily application.

Approval duration: 4 weeks

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Actinic Keratosis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Tolak therapy for the current requested use has not exceeded 4 weeks;
4. If request is for a dose increase, new dose does not exceed once daily application.

Approval duration: Up to 4 weeks total per treatment course

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DNA: Deoxyribonucleic acid
DPD: dihydropyrimidine dehydrogenase deficiency
FDA: Food and Drug Administration
RNA: Ribonucleic acid

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluorouracil 5% topical cream (Efudex®)	Actinic Keratosis: Apply to lesions topically BID for 2 to 6 weeks	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindications:
  - Dihydropyrimidine dehydrogenase (DPD) deficiency
  - Pregnancy
- Boxed Warnings: none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Actinic Keratosis Lesions	Apply topically QD for 4 weeks in an amount sufficient to cover the lesions with a thin film, massaging uniformly into the skin	As specified

VI. Product Availability

Cream (4%): 40 g

VII. References

1. Tolak Prescribing Information. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc.; October 2019. Available at: https://dailymed.nlm.nih.gov/. Accessed July 16, 2021.

2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: www.clinicalpharmacology-ip.com/. Accessed July 16, 2021.
3. Jansen MHE, Kessels JPHM, Nelemans PJ, et al. Randomized Trial of Four Treatment Approaches for Actinic Keratosis. N Engl J Med. 2019 Mar 7;380(10):935-946.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: References reviewed and updated.	08/20	11/20
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	