Drug Therapy Guidelines	Applicable	Solaraze®, diclofenac 3% gel
Medical Benefit		**Effective:** 11/1/18
Pharmacy- Formulary 1	x	**Next Review:** 9/18
Pharmacy- Formulary 2	x	**Date of Origin**: 6/18
Pharmacy- Formulary 3/Exclusive	x	**Review Dates:** 6/18, 9/18
Pharmacy- Formulary 4/AON	x	

I. Medication Description

Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits cyclooxygenase-1 and 2 (COX-1, COX-2) and prevents upregulation of the arachidonic acid cascade of reactions. While the exact mechanism by which diclofenac 3% gel works is unknown, it is theorized that production of prostaglandins and inflammatory markers from arachidonic acid may play a role in UVB-induced skin cancers.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided for the treatment of actinic keratosis when the following criteria are met:

- Medication is prescribed by a dermatologist or oncologist **AND**
- Documentation (e.g. chart notes) is provided confirming the diagnosis of actinic keratosis **AND**
- The member is not a candidate for destructive therapies (e.g. surgery, cryotherapy, dermabrasion, photodynamic therapy) **AND**
- When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results **AND**
- The member has tried and failed at least one (1) of the plan-preferred medications (topical 5-fluorouracil, imiquimod, or Picato) **OR** at least ONE of the following criteria have been met:
    - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
    - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member's prescription drug regimen.
    - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
    - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where "stable" is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of "stable").

- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member's adherence or to compliance with the member's plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member's ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

Coverage is available for one 100gram tube per 30 days

V. Coverage Duration

Coverage is available for 3 months and will not be renewed

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

Solaraze is available as:

- Diclofenac 3% topical gel: 100gram tube
- Solaraze 3% topical gel: 100gram tube

VIII. Summary of Policy Changes

- 8/15/18: new policy
- 11/1/18: no policy changes

IX. References

1. Solaraze ® (diclofenac sodium gel). Package insert. PharmaDerm a division of Fougera Pharmaceuticals Inc. Melville, NY 11747. Revised 4/2016.
2. Gold Standard, Inc. Solaraze. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed: May 14th, 2018.
3. Jorizzo, Joseph. Treatment of Actinic Keratosis. In: UpToDate, Corona, Rosamaria (Ed), UpToDate, Waltham, MA, April 2018.
4. Ceilley RI, Jorizzo JL. Current issues in the management of actinic keratosis. J Am Acad Dermatol 2013; 68:S28.