BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/15/18**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

SOLARAZE® (diclofenac sodium) gel 3% transdermal
Diclofenac gel 3% transdermal

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Solaraze (diclofenac sodium) and Diclofenac

Medication class:
- Dermatologicals, Antineoplastic or Premalignant Lesion Agents - Topical

FDA-approved indication(s):
- For the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy.

Recommended Dose:
- Apply to lesion areas twice daily.
- It is to be smoothed onto the affected skin gently.
- The amount needed depends upon the size of the lesion site. Assure that enough gel is applied to adequately cover each lesion. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site.
- The recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

Available Dosage Forms:
- Gel, 3%. Each gram of gel contains 30 mg of diclofenac sodium.

Warnings and Precautions:
- Cardiovascular Thrombotic Events
  - Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
  - Solaraze is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Criteria:

- **Criteria for initial therapy:** Solaraze and Diclofenac 3% gel is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a Dermatologist
2. Individual is 18 years of age or older
3. A confirmed diagnosis of actinic keratoses (AK)
4. Individual has failure, contraindication or intolerance to **BOTH** Tolak 4% cream and imiquimod 5% cream
5. For Solaraze: Individual has failure, contraindication or intolerance to Diclofenac 3% gel
6. There are **NO** contraindications.
   - Contraindications include:

SOLARAZE® (diclofenac sodium) gel 3% transdermal
Diclofenac gel 3% transdermal (cont.)

- Patients with a known hypersensitivity to **diclofenac or other NSAIDS**, benzyl alcohol, polyethylene glycol monomethyl ether 350 and/or hyaluronate sodium.
- Nonintact or damaged skin
- Eczema or dermatitis
- Infected lesions, burns or wounds
- In the setting of coronary artery bypass graft (CABG) surgery.

Initial approval duration: Up to one 100 gm tube/30 days for 90 days

- **Criteria for continuation of coverage (renewal request):** Solaraze and Diclofenac 3% gel is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by Dermatologist
2. Individual's condition has not worsened while on therapy
    - Worsening is defined as:
        - Actinic keratosis lesions are larger
3. It has been over 30 days since stopping the initial therapy with diclofenac 3% gel (or Brand Solaraze)
4. Individual has been adherent with the medication for 90 days
5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications or adverse effect:
        - Signs and symptoms may include:
            - Hematuria
            - Dyspnea
            - Pneumonia
            - Arthralgia
6. There are no significant interacting drugs

Renewal duration: Up to one 100 gm tube for 2 months

Resources:

Solaraze. Package Insert. Revised by manufacturer 5/2016. Accessed 2/9/18.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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