PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

(diclofenac sodium gel 3%)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 621-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Diclofenac sodium gel 3% (generic Solaraze Gel) is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy.

COVERAGE CRITERIA

The requested drug [diclofenac sodium gel 3 percent (generic Solaraze)] will be covered with prior authorization when being prescribed for the treatment of actinic keratoses (AK).

Quantity limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Diclofenac sodium gel 3% is indicated for the topical treatment of actinic keratoses (AK).

Diclofenac sodium gel 3% is applied to lesion areas twice daily. Normally 0.5 grams of gel is used on each 5 cm x 5 cm lesion site. Up to three major body areas were studied in any patient. A major body area was defined as one of five 5 cm x 5 cm regions: scalp, forehead, face, forearm and hand.

Diclofenac sodium gel 3% is available in tubes of 100 grams. 100 grams should be sufficient to adequately cover three areas at a size of 5 cm x 5 cm for 30 days.

The recommended duration of therapy is from 60 days to 90 days. The duration of approval will be 3 months.

REFERENCES

1. Solaraze [package insert]. Melville, NY: PharmaDerm; May 2016.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed May 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed May 2019.

Written by:	UM Development (CT)
Date Written:	01/2010
Revised:	(MS) 02/2011 (new MDC-1 created from Silverscript), 09/2011; (CT) 08/2012; (MS) 06/2013, 06/2014; (RP) 06/2015; (MS) 06/2016, (TM) 06/2017 (add limit, revise duration), (SF) 06/2018 (no clinical changes); (DFW) 06/2019 (removed MDC designation from title/document)
Reviewed:	Medical Affairs (KP) 01/2010, 02/2011, 09/2011, 08/2012; (LS) 06/2013; (DC) 06/2014, 06/2015; (ME) 06/2016, (AN) 06/2017, (AN) 06/2019 External Review: 03/2010, 05/2011, 02/2012, 12/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 08/2019

CVS caremark™

CRITERIA FOR APPROVAL

1	Is the requested drug [diclofenac sodium gel 3 percent (generic Solaraze)] being prescribed for the treatment of actinic keratoses (AK)?	Yes	No
2	Does the patient require more than the plan allowance of 100 grams per month? [RPh Note: If yes, then deny and enter a partial approval for 100 grams per 25 days of diclofenac sodium gel 3 percent.]	Yes	No

Guideline for Approval	
Duration of Approval	**3 Months**
Set 1	
Yes to Question(s)	**No to Question(s)**
1	2

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have actinic keratoses (AK). Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Deny	Approve, 3 Months, 100 grams/25 days 300 grams/75 days	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 100 grams/month of diclofenac sodium gel 3 percent. You have been approved for the maximum quantity that your plan covers for a duration of 3 months. Your request for additional quantities of the requested drug and strength has been denied. [Short description: Over max quantity]

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*