

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Comments	Quantity Limit
generic diclofenac solution 1.5%	Preferred (all preferred agents require prior authorization)	May be subject to quantity limit
generic diclofenac gel 1%		
Diclofenac epolamine 1.3% patch	Non-Preferred	
Flector (diclofenac epolamine) patch		
Licart (diclofenac epolamine 1.3%) topical system		
Voltaren gel		

APPROVAL CRITERIA

Requests for **all** topical NSAIDs may be approved if the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one (1) preferred generic **oral** NSAID;

Preferred Agents: all generically available Ibuprofen (except Infants Advil 50mg/1.25 ML), Diclofenac Potassium, Diclofenac Sodium, Etodolac, Etodolac ER, Fenoprofen Calcium, Flurbiprofen, Indomethacin, Ketoprofen, Ketorolac Tromethamine, Meclofenamate Sodium, Meloxicam, Nabumetone, Naproxen Sodium all generic formulations, Naproxen, Naproxen DS 550mg, Oxaprozin, Piroxicam, Sulindac, Tolmetin Sodium.

OR

- II. Individual is at an increased risk for adverse events with oral NSAID use (such as, cardiovascular adverse events, gastrointestinal adverse events, renal adverse events);

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OR

III. Individual is 75 years of age or older (ACR 2012).

Requests for a non-preferred topical NSAIDs may be approved if the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one (1) preferred **topical** NSAID; **OR**
- II. The preferred topical NSAIDs are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does.

Notes:

All NSAIDs (topical and oral) carry a black box warning regarding cardiovascular and gastrointestinal risks. NSAIDs can increase the risks of cardiovascular thrombotic events, myocardial infarction and stroke. Risks increase with duration of use and those with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. NSAIDs are contraindicated in the peri-operative setting of coronary artery bypass graft (CABG) surgery. NSAIDs also cause increased risk of serious gastrointestinal adverse events including bleeding, ulceration and perforation of the stomach or intestines. Elderly individuals are at greater risk for serious gastrointestinal events.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 18, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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5. Derry S, Conaghan P, Da Silva JA, Wiffen PJ, Moore RA. Topical NSAIDs for chronic musculoskeletal pain in adults. *Cochrane Database Syst Rev.* 2016 Apr 22; 4: CD007400.
6. Hochberg MC, Altman RC, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res.* 2012 Apr; 64(4): 465-74. Available from: <https://www.rheumatology.org/practice-quality/clinical-support/clinical-practice-guidelines/osteoarthritis>. Accessed April 18, 2019.
7. Lanza FL, Chan FKI, Quigley EMM, Practice Parameters Committee of the American College of Gastroenterology. Guidelines for Prevention of NSAID-Related Ulcer Complications. *Am J Gastroenterol.* 2009; 104:728 – 738.doi: 10.1038/ajg.2009.115. Available from: <http://s3.gi.org/physicians/guidelines/NSAIDJournalPublicationFebruary2009.pdf>.
8. The NCCN Drugs & Biologics Compendium (NCCN Compendium™)© 2019 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
9. Klinge SA, Sawyer GA. Effectiveness and safety of topical versus oral nonsteroidal anti-inflammatory drugs: a comprehensive review. *Phys Sportsmed.* 2013 May; 41(2):64-74.

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