Topical NSAID Step Therapy with Quantity Limit Program Summary

Step Therapy applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

Quantity limits apply to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
05-01-2024	04-01-2017

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Flector® (diclofenac epolamine) 180 mg Topical patch (1.3% in aqueous base)	Topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years and older.		1
Licart® (diclofenac epolamine) Topical system	Topical treatment of acute pain due to minor strains, sprains, and contusions		12
Pennsaid®* (diclofenac sodium) 1.5% Topical solution 2% Topical solution	Treatment of signs and symptoms of osteoarthritis of the knee(s). Treatment of pain of osteoarthritis of the knee(s).	*generic available	2,7
Voltaren Gel®* (diclofenac sodium) 1% Topical gel	Relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel has not been evaluated for use on the spine, hip, or shoulder.	*generic available	3

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See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Acute Pain	The American Family Physician review suggests that data was insufficient to make conclusions regarding comparisons of topical vs. oral NSAIDs, a specific topical NSAID vs. another, or different formulations of the same topical NSAID.(11) A 2016 review suggests topical NSAIDs are good options for acute musculoskeletal pain in patients at risk of adverse effects from oral NSAIDs who present with a focal area pain. Topical agents are only effective for treating more superficial structures.(6) A Cochrane Review (2015) evaluating topical NSAIDs for acute pain due to strains, sprains, or sports/overuse type injuries found there was insufficient data to reliably compare individual topical NSAIDs with each other or to the same oral NSAID.(5)

Osteoarthritis (OA)	The American Academy of Orthopedic Surgeons recommended the following:
	
	• For the management of knee OA:(8)
	  ○ NSAIDs (oral or topical) or tramadol are recommended for patients with symptomatic OA of the knee. [Strong recommendation; high level evidence]
	  ○ The panel was unable to recommend for or against the use of acetaminophen, opioids, or pain patches for patients with symptomatic OA of the knee. (Inconclusive recommendation)
	• For the management of hip OA:(9)
	  ○ NSAIDs improve short-term pain, function, or both
	
	The American College of Rheumatology and the Arthritis Foundation states the following for the management of OA in the hand, hip, or knee:(4)
	
	• Usual care includes the use of oral NSAIDs and/or acetaminophen
	• Oral NSAIDs are strongly recommended for knee, hip, and/or hand OA
	• Topical NSAIDs are strongly recommended for knee OA and conditionally recommended for hand OA
	• Topical NSAIDs should be considered prior to use of oral NSAIDs to limit systemic exposure
	
	A 2016 review suggests topical NSAIDs are as effective as oral NSAIDs and generally safer, but only effective for OA of more superficial joints such as hands and knees.(5) For multiple or deep arthritic joints, oral NSAIDs are easier to use and more efficacious.(6) The American Geriatric Society updated the Beers Criteria in 2015. They recommended that the chronic use of all NSAIDs, including high dose aspirin, should be avoided because of the risk of gastrointestinal bleeding. High-risk groups include: age above 75 years, corticosteroid use, current use of anticoagulants or antiplatelet agents.(6)

Safety	Flector, Licart, Pennsaid, and Voltaren gel contain the following black box warning:(1-3,7,12)
	
	• Cardiovascular risk
	  ○ Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
	  ○ NSAIDs are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
	• Gastrointestinal Risk
	  ○ NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach

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	or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events. Flector and Licart carry the following contraindications: • Known hypersensitivity to diclofenac or any components of the product • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs • In the setting of CABG surgery • For use on non-intact or damaged skin Pennsaid and Voltaren gel carry the following contraindications: • Known hypersensitivity to diclofenac or any components of the product • History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs • In the setting of coronary artery bypass graft (CABG) surgery

REFERENCES

Number	Reference
1	Flector prescribing information. Pfizer, Inc. April 2021.
2	Diclofenac 1.5% prescribing information. SOLA Pharmaceuticals, LLC. June 2021.
3	Voltaren Gel prescribing information. Endo Pharmaceuticals Inc. November 2021.
4	Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. Arthritis & Rheumatology. 2020; 72(2):220-233.
5	Adili A, Bhandari M. Cochrane in CORR®: Topical NSAIDs for Chronic Musculoskeletal Pain in Adults. Clin Orthop Relat Res. 2018 Nov;476(11):2128-2134. doi: 10.1097/CORR.0000000000000486.
6	Wongrakpanich S, Wongrakpanich A, Melhado K, Rangaswami J. A Comprehensive Review of Non-Steroidal Anti-Inflammatory Drug Use in The Elderly. Aging Dis. 2018 Feb 1;9(1):143-150. doi: 10.14336/AD.2017.0306.
7	Pennsaid (2%) prescribing information. Horizon USA, Inc. Jan 2022.
8	American Academy of Orthopedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty). August 2021. https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf
9	Management of osteoarthritis of the hip evidence-based clinical practice guideline. American Academy of Orthopedic Surgeons. March, 2017. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-hip/oa-hip-cpg_6-11-19.pdf
10	Reference no longer used.
11	Topical NSAID for acute musculoskeletal pain in adults. American Family Physician. 2016 Jul 1; 94(1): Available at: https://www.aafp.org/pubs/afp/issues/2016/0701/od1.html
12	Licart prescribing information. IBSA INST BIO. April 2021.

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Flector	diclofenac epolamine patch	1.3 %	M ; N ; O	M		
Licart	diclofenac epolamine patch	1.3 %	M ; N ; O	N		
Pennsaid	Diclofenac Sodium Soln 2%	2 %	M ; N ; O	O ; Y		
Voltaren	diclofenac sodium gel	1 % ; 1.6 %	M ; N ; O	N ; O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Diclofenac Sodium Soln 1.5%	1.5 %	2	Bottles	30	DAYS			
Flector	Diclofenac Epolamine Patch 1.3%	1.3 %	60	Patches	30	DAYS			
Licart	diclofenac epolamine patch	1.3 %	30	Patches	30	DAYS			
Licart	Diclofenac Epolamine Patch 24HR 1.3%	1.3 %	30	Patches	30	DAYS			
Pennsaid	Diclofenac Sodium Soln 2%	2 %	2	Bottles	30	DAYS			
Voltaren	Diclofenac Sodium Gel 1%	1 %	10	Tubes	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Flector	diclofenac epolamine patch	1.3 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Licart	diclofenac epolamine patch	1.3 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Pennsaid	Diclofenac Sodium Soln 2%	2 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Voltaren	diclofenac sodium gel	1 % ; 1.6 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

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CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Diclofenac Sodium Soln 1.5%	1.5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Flector	Diclofenac Epolamine Patch 1.3%	1.3 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Licart	diclofenac epolamine patch	1.3 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Licart	Diclofenac Epolamine Patch 24HR 1.3%	1.3 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Pennsaid	Diclofenac Sodium Soln 2%	2 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Voltaren	Diclofenac Sodium Gel 1%	1 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENTS -a **Flector®, Diclofenac Epolamine Patch** **Licart™** (diclofenac topical system) **Pennsaid® 2%** (diclofenac solution) -b **Voltaren Gel®** (diclofenac gel 1%) -b a – diclofenac solution 1.5% available as generic; included as a prerequisite in the step therapy program b – generic available; included as a prerequisite in the step therapy program **Target Agents** will be approved when ONE of the following are met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of a generic topical NSAID (non-steroidal anti-inflammatory drug) agent as indicated by: A. Evidence of a paid claim(s) **OR** B. The prescriber stated that the patient has tried a generic topical NSAID agent AND the generic topical NSAID agent was discontinued due to lack of effectiveness or an adverse event **OR**

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Module	Clinical Criteria for Approval
	3. The prescriber has provided documentation that ALL generic topical NSAID agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable) **OR** 3. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

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