 <p>JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE</p>	Johns Hopkins HealthCare LLC Pharmacy Public Pharmacy Management Drug Policies	<i>Policy Number</i>	MEDS047
		<i>Effective Date</i>	01/16/2013
		<i>Review Date</i>	10/20/2021
	<i>Subject</i> Topical Non-Steroidal Anti-inflammatory Drugs (NSAIDs): (Diclofenac patch, Diclofenac gel, Diclofenac solution, Sprix Flector, Licart, Pennsaid)	<i>Revision Date</i>	12/13/2022
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Keywords: Diclofenac 3% gel, Diclofenac patch, Flector, Licart, Pennsaid, Sprix


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I. POLICY

- A. Diclofenac epolamine 1.3% patch (generic Flector), Sprix (ketorolac tromethamine nasal spray), Pennsaid 2% solution (diclofenac sodium 2%), Diclofenac sodium 1.5% solution, Licart patch (diclofenac epolamine 1.3%), and Diclofenac sodium 3% gel will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
 2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA


- A. **Diclofenac epolamine 1.3% patch** (generic Flector) may be approved for patients meeting the following:
1. Patient is 6 years of age or older
 2. Documentation has been submitted showing a diagnosis of acute pain due to minor strains, sprains, and contusions
 3. Documentation has been submitted showing the patient has one of the following:
 - a. Previous trial and inadequate response to oral diclofenac, as well as two other formulary oral NSAIDs
 - b. History of severe reaction to an oral NSAID (e.g. hepatitis, edema, or gastrointestinal hemorrhage, perforation or ulcer)
 - c. An inability to take oral medication
- B. **Flector** may be approved for patients meeting the following:
1. Patient is 6 years of age or older
 2. Documentation has been submitted showing a diagnosis of acute pain due to minor strains, sprains, and contusions
 3. Documentation has been submitted showing the patient has one of the following:
 - a. Previous trial and inadequate response to oral diclofenac, as well as two other formulary oral NSAIDs

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- b. History of severe reaction to an oral NSAID (e.g. hepatitis, edema, or gastrointestinal hemorrhage, perforation or ulcer)
- c. An inability to take oral medication
4. Documentation has been submitted showing trial and failure with generic diclofenac epolamine 1.3% patch
- C. **Licart** may be approved for patients meeting the following:
 1. Patient is 18 years of age or older
 2. Documentation has been submitted showing a diagnosis of acute pain due to minor strains, sprains, and contusions
 3. Documentation has been submitted showing the patient has one of the following:
 - a. Previous trial and inadequate response to oral diclofenac, as well as two other formulary oral NSAIDs
 - b. History of severe reaction to an oral NSAID (e.g. hepatitis, edema, or gastrointestinal hemorrhage, perforation or ulcer)
 - c. An inability to take oral medication
 4. Documentation has been submitted showing trial and failure with generic diclofenac epolamine 1.3% patch
- D. **Diclofenac sodium 2% (generic of Pennsaid)** and **Diclofenac sodium 1.5% solution** may be approved for patients meeting the following:
 1. Patient is 18 years of age or older
 2. Documentation has been submitted showing a diagnosis of osteoarthritis (OA) pain of the knee
 3. Documentation has been submitted showing trial and inadequate response, or intolerance with both of the following treatments:
 - a. Oral diclofenac, as well as two other formulary oral NSAIDs
 - b. Generic diclofenac 1% gel
 4. Caveat for brand Pennsaid 2%: In addition to the above requirements, patient would need to have a documented trial and inadequate response, or contraindication, to the generic diclofenac sodium 2% product
- E. **Sprix** may be approved for patients meeting the following:
 1. Patient is 18 years of age or older
 2. Documentation has been submitted showing a diagnosis of moderate to severe pain that requires short-term management
 3. Documentation has been submitted showing the patient has one of the following:
 - a. Previous trial and inadequate response to three formulary oral NSAIDs
 - b. History of severe reaction to an oral NSAID (e.g. hepatitis, edema, or gastrointestinal hemorrhage, perforation or ulcer)
 - c. An inability to take oral medication
- F. **Diclofenac sodium 3% gel** may be approved for patients meeting the following:
 1. Patient is 18 years of age or older
 2. Documentation has been submitted showing a diagnosis of actinic keratoses
 3. Documentation has been submitted showing trial and inadequate response, or intolerance with both topical fluorouracil and imiquimod cream

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Diclofenac epolamine 1.3% patch and Flector: Approval for acute pain will be restricted to 15 days with a maximum of 30 patches
- B. Licart: Approval for acute pain will be restricted to 15 days with a maximum of 15 systems
- C. Pennsaid 2%, and generic diclofenac 1.5%: I
 1. Initial approval for pain due to OA will be restricted to 12 months with a maximum of 2 bottles per 30 days

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2. Approval for continuation of therapy can be extended in 12-month intervals with documentation showing the patient's positive clinical response and tolerance of treatment
- D. Sprix: Approval for moderate to severe pain will be restricted to 5 days with a maximum of 5 bottles
- E. Diclofenac sodium 3%: Approval for AK will be restricted to 3 months with a maximum of one 100-gram tube per 30 days

IV. EXCLUSIONS

- A. Topical NSAIDs products will not be approved for the following:
 1. Concurrent use of oral NSAIDs
 2. Peri-operative pain in the setting of coronary artery bypass graft (CABG)
 3. Known hypersensitivity to Aspirin, NSAIDs, or EDTA
 4. Additional product-specific exclusions:
 1. Sprix will also not be approved for the following:
 - a. Greater than 5 days of use
 - b. Peptic ulcer disease (PUD) or GI bleeds
 - c. Advanced renal impairment or at risk for renal failure
 - d. Use as a prophylactic analgesic before any major surgery
 - e. People who are at high risk for bleeding or have cerebrovascular bleeding
 2. Diclofenac epolamine 1.3% patch, Flector, and Licart will also not be approved for chronic pain, or pain associated with venipuncture
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.


V. REFERENCES

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VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
03/01/2014	Changed title to "Topical NSAIDs"

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04/20/2016	Removed background information
1/18/2017	Added generic diclofenac 1% gel to the formulary; Updated the clinical criteria for Pennsaid; Clarified the covered indication for Flector
07/27/2017	Updated Exclusions section regarding physician samples
11/12/2019	Clarified coverage criteria for Pennsaid products
10/20/2021	Added criteria for Licart and diclofenac sodium 3%
12/13/2022	Clarified coverage for the generic and branded Pennsaid products

Review/Revision Dates: 03/01/2014, 4/20/2016, 1/18/2017, 07/27/2017, 11/12/2019, 10/20/2021, 12/13/2022