



## Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

**Policy #** 00353

**Original Effective Date:** 06/25/2013

**Current Effective Date:** 10/09/2023

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **For Patients With "Step Therapy" (generic before brand) ONLY:**

Based on review of available data, the Company may consider brand name non-steroidal anti-inflammatory drugs (NSAIDs), (including, but not limited to Celebrex<sup>®</sup> [celecoxib], Voltaren Gel<sup>®</sup> [diclofenac sodium], Motrin<sup>®</sup> [ibuprofen], Mobic<sup>®</sup> [meloxicam], Flector<sup>®</sup> Patch or its branded generic [diclofenac epolamine], Licart<sup>®</sup> Patch [diclofenac epolamine], Pennsaid<sup>®</sup> topical solution [diclofenac sodium], and Sprix<sup>®</sup> nasal spray or its branded generic [ketorolac])<sup>‡</sup> to be **eligible for coverage\*\*** when one of the below patient selection criteria is met:

#### **Patient Selection Criteria**

Coverage eligibility will be considered for brand name NSAIDs when ONE of the following criteria is met:

- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient; OR
- Patient has tried and failed (e.g., intolerance or inadequate response) one generic prescription strength NSAID for the current condition (over-the-counter [OTC] NSAIDs taken in prescription strength doses do meet this criteria); OR
- Requested drug is a topical brand name NSAID (e.g., Flector Patch or its branded generic, Licart Patch, Voltaren Gel, Pennsaid topical solution, Sprix nasal spray or its branded generic): Patient has difficulty swallowing or cannot swallow.

### **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of brand name NSAIDs when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.\*\***

### **When Services May Be Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

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- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### **For Patients With "Prior Authorization" ONLY OR BOTH "Prior Authorization" and "Step Therapy":**

#### **Oral/Rectal:**

Based on review of available data, the Company may consider the following branded NSAIDs: Nalfon<sup>®</sup> (fenoprofen) capsule/tablet, Fenoprofen 200 mg capsule, Fenortho<sup>®</sup> (fenoprofen) capsule, Vivlodex<sup>™</sup> (meloxicam) capsule, Zorvolex<sup>™</sup> (diclofenac) capsule, Zipsor<sup>®</sup> (diclofenac potassium) capsule, branded Diclofenac 35 mg capsule, Tivorbex<sup>™</sup> (indomethacin) capsule, Indocin<sup>®</sup> (indomethacin) suspension, Indocin<sup>™</sup> (indomethacin) suppository, branded Indomethacin 20 mg capsule, Naprelan<sup>®</sup> (naproxen extended/controlled release) tablet, Naprosyn (naproxen) suspension, Relafen (nabumetone) tablet, Relafen DS<sup>™</sup> (nabumetone) tablet, Duexis<sup>®</sup> (ibuprofen/famotidine) tablet, Vimovo<sup>®</sup> (naproxen/esomeprazole) tablet, Mobic (meloxicam) tablet, Celebrex (celecoxib) capsule, Lodine<sup>®</sup> (etodolac) tablet, Feldene<sup>®</sup> (piroxicam) capsule, Anaprox DS<sup>®</sup> (naproxen) tablet, Naprosyn<sup>®</sup> (naproxen) tablet, EC-Naprosyn<sup>®</sup> (naproxen enteric coated) tablet, Daypro<sup>®</sup> (oxaprozin) tablet, Ponstel<sup>®</sup> (mefenamic acid) capsule, Arthrotec<sup>®</sup> (diclofenac/sodium/misoprostol) tablet, and the following generic products: lofena (diclofenac potassium 25 mg) tablet, diclofenac potassium 25 mg tablet, diclofenac potassium capsule, fenoprofen tablet, fenoprofen 400 mg capsule, meclofenamate capsule, ketoprofen immediate release 25 mg capsule, meloxicam 5 mg and 10 mg capsule, naproxen enteric coated tablet (delayed release, i.e., generic for EC-Naprosyn), ketoprofen extended release capsule, mefenamic acid capsule, tolmetin capsule, tolmetin tablet, naproxen/esomeprazole tablet, ibuprofen/famotidine tablet, and naproxen sodium tablet (extended/controlled release, e.g., generic for Naprelan) to be **eligible for coverage\*\*** when the patient selection criteria for the selected drug is met:

Select Generic NSAIDs: **NO PA required**	diclofenac potassium tablet (EXCLUDING lofena), diclofenac sodium tablet (enteric coated), diclofenac 24 hour release tablet, etodolac capsule/tablet (immediate release only), ketoprofen capsule (immediate release 50 mg and 75 mg only), piroxicam capsule, indomethacin capsule (immediate release 25 mg and 50 mg and sustained release 75 mg), nabumetone tablet, naproxen tablet (immediate release), naproxen suspension, naproxen delayed release tablets (EXCLUDING the naproxen enteric coated tablet [i.e.,
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	generic for EC-Naprosyn]), sulindac tablet, ketorolac tablet, meloxicam tablet/suspension, flurbiprofen tablet, ibuprofen tablet/suspension, celecoxib capsule
Non-Select Generic NSAIDs: **PA required**	diclofenac potassium capsule, lofena (diclofenac potassium 25 mg) tablet, diclofenac potassium 25 mg tablet, fenoprofen tablet, fenoprofen 400 mg capsule, meclofenamate capsule, ketoprofen immediate release 25 mg capsule, meloxicam 5 mg and 10 mg capsule, naproxen enteric coated tablet (delayed release, i.e., generic for EC-Naprosyn), ketoprofen capsule (extended release), mefenamic acid capsule, tolmetin capsule, tolmetin tablet, naproxen/esomeprazole tablet, naproxen sodium tablet (extended/controlled release, e.g., generic for Naprelan)
Other Generic NSAIDs: **NO PA required**	etodolac extended release tablet, oxaprozin tablet, diclofenac/misoprostol tablet

*\*Note that products required to be tried and failed must be prescription products. Over the counter products DO NOT count\**

### Patient Selection Criteria

Coverage eligibility will be considered for the following drugs when their respective criteria are met:

#### Single-Source Brands (brands withOUT generic equivalents):

*\*Note that products required to be tried and failed must be tried for at least ONE month each (unless otherwise noted)\**

- Fenoprofen 200 mg capsule, Fenortho capsule:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list.
- Zorvolex capsule, branded Diclofenac 35 mg capsule
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be diclofenac potassium tablets (EXCLUDING lofena), diclofenac sodium tablets [enteric coated], or diclofenac 24 hour release tablets).
- Tivorbex capsule, Indocin suspension, branded Indomethacin 20 mg capsule:

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- Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be indomethacin capsules [immediate release 25 mg or 50 mg or sustained release 75 mg]).
- Indocin suppository:
  - Patient can’t chew or swallow AND is currently NOT taking medications in tablet and/or capsule form.
- Relafen DS tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be nabumetone tablets).

### Non-Select Generics:

*\*Note that products required to be tried and failed must be tried for at least ONE month each (unless otherwise noted)\**

- diclofenac potassium capsule:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be diclofenac potassium tablets (EXCLUDING lofena), diclofenac sodium tablets [enteric coated], or diclofenac 24 hour release tablets).
- fenoprofen tablet, fenoprofen 400 mg capsule, mefenamic acid capsule, meclofenamate capsule, tolmetin capsule/tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list.
- ketoprofen capsule (extended release), ketoprofen capsule 25 mg (immediate release):
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be ketoprofen immediate release 50 mg or 75 mg capsules).
- meloxicam 5 mg and 10 mg capsule:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be meloxicam tablets).
- lofena (diclofenac potassium 25 mg) tablet, diclofenac potassium 25 mg tablet:

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- Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be diclofenac potassium tablets (EXCLUDING lofena), diclofenac sodium tablets [enteric coated], or diclofenac 24 hour release tablets).
- naproxen/esomeprazole tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH of the following after at least SIX months of combination therapy with each trial:
    - Prescription generic proton pump inhibitor AND prescription generic naproxen (immediate release) at a dose of 250 mg, 375 mg, or 500 mg twice daily; AND
    - One additional trial of a different generic product from the “select generic” NSAID oral list in combination with a different prescription generic proton pump inhibitor.
- ibuprofen/famotidine tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH of the following after at least SIX months of combination therapy with each trial:
    - Prescription generic ibuprofen at a dosage of 800 mg three times daily; AND prescription generic famotidine at a total daily dose of at least 40 mg; AND
    - One additional trial of a different generic product from the “select generic” NSAID oral list in combination with a different prescription generic H2 blocker.
- naproxen sodium extended release tablet (e.g., generic Naprelan), naproxen enteric coated tablet (delayed release, i.e., generic for EC-Naprosyn):
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen immediate release tablets or naproxen delayed release tablets EXCLUDING the naproxen enteric coated tablet [i.e., generic for EC-Naprosyn]).

### Multi-Source Brands (brands WITH generic equivalents)

*\*Note that products from the “select generic” NSAID oral list must be tried for at least ONE month each (unless it is the generic equivalent or similar generic ingredient) AND the generic equivalent/similar generic ingredient product must be tried for at least SIX months. An exception to this is Vimovo, where criteria are specified below.\**

- Nalfon tablet:

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- Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list.
- Mobic tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be meloxicam tablets).
- Celebrex capsule:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be celecoxib capsules).
- Lodine tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be etodolac capsule/tablets [immediate release]).
- Feldene capsule:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be piroxicam capsules).
- Anaprox DS, Naprosyn, EC-Naprosyn tablets:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen immediate release tablets or naproxen delayed release tablets EXCLUDING the naproxen enteric coated tablet [i.e., generic for EC-Naprosyn]).
- Naprosyn suspension:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen suspension).
- Relafen tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be nabumetone tablets).
- Daypro tablet:

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- Patient has tried and failed (e.g., intolerance or inadequate response) TWO products from the “select generic” NSAID oral list; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic oxaprozin tablets.
- Ponstel capsule:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO products from the “select generic” NSAID oral list; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic mefenamic acid capsules.
- Arthrotec tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO products from the “select generic” NSAID oral list PLUS a trial and failure (e.g. intolerance or inadequate response) with TWO generic proton pump inhibitors and/or H2 blockers); AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic diclofenac/misoprostol.
- Vimovo tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH of the following after at least SIX months of combination therapy with each trial:
    - Prescription generic proton pump inhibitor AND prescription generic naproxen (immediate release) at a dose of 250 mg, 375 mg, or 500 mg twice daily; AND
    - One additional trial of a different generic product from the “select generic” NSAID oral list in combination with a different prescription generic proton pump inhibitor.
- Nalfon capsule
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list.
- Vivlodex capsule
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be meloxicam tablets).
- Zipsor capsule

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- Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be diclofenac potassium tablets (EXCLUDING lofena), diclofenac sodium tablets [enteric coated], or diclofenac 24 hour release tablets).
- Naprelan tablet
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen immediate release or naproxen delayed release tablets EXCLUDING the naproxen enteric coated tablet [i.e., generic for EC-Naprosyn]).
- Duexis tablet:
  - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH of the following after at least SIX months of combination therapy with each trial:
    - Prescription generic ibuprofen at a dosage of 800 mg three times daily; AND prescription generic famotidine at a total daily dose of at least 40 mg; AND
    - One additional trial of a different generic product from the “select generic” NSAID oral list in combination with a different prescription generic H2 blocker.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of the above listed oral/rectal NSAID products when the patient selection criteria are not met to be **not medically necessary**.\*\*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### Topical:

Based on review of available data, the Company may consider the following branded topical NSAIDs: Sprix<sup>®</sup> (ketorolac) nasal spray, branded Ketorolac nasal spray, Pennsaid (diclofenac) 2% solution, Flector (diclofenac epolamine) Patch, branded Diclofenac Epolamine Patch, Licart (diclofenac epolamine) Patch, Voltaren (diclofenac) 1% gel, and the following generic product:

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diclofenac 2% solution to be **eligible for coverage\*\*** when the patient selection criteria for the selected drug are met:

Select Topical NSAID Generics:	diclofenac 1.5% drops, klofensaid 1.5% drops, diclofenac 1% gel
**NO PA required**	
Select Topical NSAID Generics:	diclofenac 2% solution
**PA required**	

### Patient Selection Criteria

Coverage eligibility will be considered for the following topical NSAID products when their respective criteria are met:

- Patient must meet the requirements of the requested drug:
  - For Sprix nasal spray, branded Ketorolac nasal spray, Pennsaid 2% solution, diclofenac 2% solution, Flector Patch, branded Diclofenac Epolamine Patch, Licart Patch, Voltaren 1% gel: Patient can't swallow AND the patient is NOT taking any other tablet/capsule products; OR
  - For Pennsaid 2% solution, diclofenac 2% solution, Flector Patch, branded Diclofenac Epolamine Patch, Licart Patch, Voltaren 1% gel: Patient has a chronic musculoskeletal pain condition (e.g., osteoarthritis) and would be applying topical products to LESS than or equal to THREE joints/sites (e.g., hand, wrist, elbow, knee, ankle, or foot each count as one joint site) AND the patient is at risk for NSAID associated toxicity (e.g., patients with previous gastrointestinal [GI] bleed, history or peptic ulcer disease, impaired renal function, cardiovascular disease [CV], hypertension, heart failure, elderly patients with impaired hepatic function or taking concomitant anticoagulants); OR
  - For Pennsaid 2% solution, diclofenac 2% solution, Flector Patch, branded Diclofenac Epolamine Patch, Licart Patch, Voltaren 1% gel: Patient is 75 years of age or older with hand or knee osteoarthritis; AND
- Patient must meet the following criteria for the requested drug (in addition to the above criteria):

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- For Sprix nasal spray, branded Ketorolac nasal spray, Pennsaid 2% solution, diclofenac 2% solution, Flector Patch, branded Diclofenac Epolamine Patch, Licart Patch:
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic topical diclofenac 1.5% drops/klofenaid for at least ONE month of therapy; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic diclofenac 1% gel for at least ONE month of therapy.
- For Voltaren 1% gel:
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic topical diclofenac 1.5% drops/klofenaid for at least ONE month of therapy; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic diclofenac 1% gel for at least SIX months of therapy.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of the above listed topical NSAID products when the patient selection criteria are not met to be **not medically necessary**.\*\*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### Other:

Based on review of available data, the Company may consider Consensi<sup>®†</sup> (amlodipine/celecoxib) to be **eligible for coverage**\*\* when the patient selection criterion is met.

### Patient Selection Criteria

Coverage eligibility will be considered for Consensi (amlodipine/celecoxib) when the following criterion is met:

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- There is clinical evidence or patient history that suggests the use of GENERIC amlodipine and GENERIC celecoxib used as separate ingredients will be ineffective or cause an adverse reaction to the patient.

### **Background/Overview**

NSAIDs are approved for use in inflammatory conditions. There are various forms of these products available, including tablets, capsules, gels, patches, nasal sprays, solutions, etc. There are a vast amount of generic products (both oral and topical) that are available in this drug class which offer time-tested alternatives to often unneeded, expensive branded products which produce very little benefit and/or value.

There are very few situations in which a topical NSAID product needs to be used. Examples include members that can't swallow, those 75 years of age and older with osteoarthritis (per the 2012 American College of Rheumatology Osteoarthritis Guidelines), and of course those with osteoarthritis who have contraindications to oral NSAIDs (GI bleed, CV disease, heart failure, etc.). Significantly lower blood levels are achieved with the topical NSAIDs versus the oral NSAIDs.

Of note, generic extended release/controlled release naproxen tablet is the generic for Naprelan 375 mg, 500 mg, and 750 mg. The generic enteric coated delayed release naproxen tablet is the generic for EC-Naprosyn (375mg and 500 mg).

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

In regard to the step therapy portion of this policy, the patient selection criteria presented takes into consideration clinical evidence or patient history that suggests the available generic NSAIDs will be ineffective or cause an adverse reaction to the patient. This policy also takes into consideration whether or not a patient is able to swallow. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name NSAID over the available generic

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NSAIDs. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

In regard to the prior authorization portion of this policy, there is no advantage in using branded products (or expensive generic products) in this class over the lower cost generic options. Adequate generic options exist in both the oral and topical NSAID classes. There is also no clinical advantage whatsoever in using Consensi over the two separate ingredients.

### **Schematic**

In order to simplify this policy (and for ease of prescribing), a listing of oral and topical NSAID products that do NOT require PA has been formulated below.

<b><u>Select Oral NSAIDs withOUT PA</u></b>	diclofenac potassium tablet (EXCLUDING lofena) diclofenac sodium tablet (enteric coated) diclofenac 24 hour release tablet etodolac capsule/tablet (immediate release only) ketoprofen capsule (immediate release 50 mg and 75 mg only) piroxicam capsule indomethacin capsule (immediate release 25 mg and 50 mg and sustained release 75 mg) nabumetone tablet naproxen tablet (immediate release) naproxen suspension naproxen delayed release tablets (EXCLUDING the naproxen enteric coated tablet [i.e., generic for EC-Naprosyn]) sulindac tablet ketorolac tablet meloxicam tablet/suspension flurbiprofen tablet ibuprofen tablet/suspension celecoxib capsule
<b><u>Select Topical NSAIDs withOUT PA</u></b>	diclofenac 1.5% drops klofensaid 1.5% drops

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diclofenac 1% gel
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## **References**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2013. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>.
2. Arthrotec<sup>®</sup> tablets [package insert]. New York, NY: Pfizer, Inc; March 2013.
3. Vimovo [package insert]. Cincinnati, OH: Wilmington, DE; March 2014.
4. Duexis tablets [package insert]. Hunt Valley, MD: Pharmaceutics International, Inc.; October 2013.
5. Flector Patch [package insert]. Piscataway, NJ: Alpharma Pharmaceuticals LLC; February 2011.
6. Voltaren Gel [package insert]. Parsippany, NJ: Novartis Consumer Health, Inc.; October 2009.
7. Pennsaid [package insert]. Hazelwood, MO: Mallinckrodt Pharmaceuticals, Inc.; October 2013.
8. Stanos SP. Topical agents for the management of musculoskeletal pain. *J Pain Symptom Manage*. 2007;33(3):342-355.
9. Sprix nasal spray [package insert]. Shirley, NY: American Regent, Inc.; April 2014.
10. Cambia for oral solution [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc.; July 2011.
11. Evers S, Afra J, Frese A, et al. EFNS guideline on the drug treatment of migraine – revised report of an EFNS task force. *Eur J Neurol*. 2009;16:968-981.
12. Data on file. Alpharma Pharmaceuticals. Received February 18, 2008.
13. Moen MD. Topical diclofenac solution. *Drugs*. 2009;69(18):2621-2632.
14. Kienzler JL, Gold M, Nollevaux F. Systemic bioavailability of topical diclofenac sodium gel 1% versus oral diclofenac sodium in healthy volunteers. *J Clin Pharmacol*. 2010;50:50-61.
15. Peniston JH, Gold MS, Alwine LK. An open-label, long-term safety and tolerability trial of diclofenac sodium 1% gel in patients with knee osteoarthritis. *Phys Sportsmed*. 2011;39:31-38.
16. Jordan KM, Arden NK, Doherty M, et al. EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis*. 2003;62:1145-1155.
17. Zhang W, Doherty M, Leeb BF, et al. EULAR evidence based recommendations for the management of hand osteoarthritis: report of a Task Force of the EULAR Standing Committee

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## Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Policy # 00353

Original Effective Date: 06/25/2013

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- for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis.* 2007;66:377-388.
18. Zhang W, Moskowitz RW, Nuki G et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage.* 2008;16:137-162.
  19. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee (non-arthroplasty). Full Guideline. December 6, 2008. Available at: <http://www.aaos.org/Research/guidelines/OAKguideline.pdf>.
  20. Richmond J, Hunter D, Irrgang J, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on the treatment of osteoarthritis (OA) of the knee. *J Bone Joint Surg Am.* 2010;92:990-993.
  21. Micromedex® Healthcare Series. Thomson Reuters (Healthcare) Inc. Available at: <http://www.thomsonhc.com>.
  22. Wolfe MM, Lichtenstein DR, Singh G. Gastrointestinal toxicity of nonsteroidal anti-inflammatory drugs. *N Engl J Med.* 1999;1888-1899.
  23. Verdict W, Moran C, Hantzsche H, et al. A double-blind comparison of the gastroduodenal safety and efficacy of diclofenac and a fixed dose combination of diclofenac and misoprostol in the treatment of rheumatoid arthritis. *Scand J Rheumatol.* 1992;21:85-91.
  24. Ashworth NL, Peloso PM, Muhajarine N, Stang M. Risk of hospitalization with peptic ulcer disease or gastrointestinal hemorrhage associated with nabumetone, Arthrotec®, diclofenac, and naproxen in a population based cohort study. *J Rheumatol.* 2005;32:2212-7.
  25. Lanza FL, Chan FKL, Quigley EMM, and the Practice Parameters Committee of the American College of Gastroenterology. Guidelines for prevention of NSAID-related ulcer complications. *Am J Gastroenterol.* 2009;104:728-738.
  26. Rinder HM, Tracey JB, Souhrada M, et al. Effects of meloxicam on platelet function in healthy adults: a randomized, double-blind, placebo-controlled trial. *J Clin Pharmacol.* 2002;42:881-886.
  27. De Meijer A, Vollaard H, De Metz M, et al. Meloxicam, 15 mg/day, spares platelet function in healthy volunteers. *Clin Pharmacol Ther.* 1999;66:425-430.
  28. Van Kraaij DJ, Hovestad-Witterland AH, De Metz M, et al. A comparison of the effects of nabumetone vs meloxicam on serum thromboxane B2 and platelet function in healthy volunteers. *Br J Clin Pharmacol.* 2002;53:644-647.

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29. Kniff-Dutmer EA, Kalsbeek-Batenburg EM, Koerts J, et al. Platelet function is inhibited by non-steroidal anti-inflammatory drugs but not by cyclo-oxygenase-2 selective inhibitors in patients with rheumatoid arthritis. *Rheumatol*. 2002;41:458-461.
30. Relafen® tablets [package insert]. Philadelphia, PA: GlaxoSmithKline; February 2006.
31. Schnitzer TJ, Donahue JR, Toomey EP, et al. Effect of nabumetone on hemostasis during arthroscopic knee surgery. *Clin Ther*. 1998;20:110-124.
32. Kniff-Dutmer EA, Martens A, vd Laar MA. Effects of nabumetone compared with naproxen on platelet aggregation in patients with rheumatoid arthritis. *Ann Rheum Dis*. 1999;58:257-259.
33. Hochberg MC, Altman RD, 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;64:465-474.
34. Derry S, Moore RA, Rabbie R. Topical NSAIDs for chronic musculoskeletal pain in adults. *Cochrane Database Syst Rev*. 012 Sep 12;9:CD007400.
35. Hochberg MC, Altman RD, 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;64:465-474.
36. Diclofenac Epolamine Patch [package insert]. Greenstone. Peapack, New Jersey. Updated August 2018.
37. Consensi [package insert]. Burke Therapeutics. Hot Springs, Arkansas. Updated December 2019.
38. Relafen DS [package insert]. Carwin Pharmaceutical Associates. Hazlet, New Jersey. Updated January 2020.
39. Ketorolac nasal spray [package insert]. Prasco Laboratories. Mason, Ohio. Updated October 2019.
40. Licart Patch [package insert]. Teikoku Seiyaku Co. Japam. Updated 2018.
41. Naproxen Sodium controlled release tablet. [package insert]. Alvogen, Inc. Morristown, New Jersey. Updated July 2019.
42. Diclofenac 35 mg capsule. [package insert]. Trivue Pharmaceuticals, Inc. Birmingham, Alabama. Updated August 2020.
43. Diclofenac Potassium 25 mg tablet. [package insert]. INA Pharmaceuticals. Fairmont, West Virginia. Updated September 2021.
44. Lofena [package insert]. Carwin Pharmaceuticals. Hazlet, New Jersey. Updated July 2021.
45. ibuprofen/famotidine [package insert]. Various Manufacturers.
46. Diclofenac sodium solution [package insert]. Apotex Corp. Weston, Florida. Updated May 2022.

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47. Fenoprofen 400 mg capsules [package insert]. Various manufacturers. Updated April 2021.

### **Policy History**

Original Effective Date: 06/25/2013

Current Effective Date: 10/09/2023

06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. New policy.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Duexis coverage to include trial of both generic ingredients for 6 months. Defined that all generic NSAIDs need to be tried for at least 6 months
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Split into step, Step/PA, and PA only. New criteria for PA of oral/rectal and topical NSAIDs.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Added new generic fenoprofen product (profeno). Added to Indocin suppository PA that the member is NOT taking medications in tablet and/or capsule form.
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Added new Nalfon tablet to policy with similar criteria for multi-source brands (try three).
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Added Qmiiz and topical branded Diclofenac Epolamine Patch to the policy.

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06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Added five new products, Relafen DS, Consensi, branded generic Ketorolac nasal spray, branded indomethacin 20 mg capsules, and generic naproxen/esomeprazole tablets to the policy.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Added PA to meclofenamate capsules, ec-naproxen, ketoprofen 25 mg. Added a new product, Licart Patch, to the policy.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Added four new products to the policy in their respective sections: branded Diclofenac 35 mg capsules (Single Source Brand section), branded Naproxen CR 750 mg tablets (Single Source Brand section), Relafen (Multi-Source Brand section), and meloxicam 5 mg and 10 mg capsules (generic section).
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Added branded Diclofenac Potassium 25 mg tablets, generic lofena (diclofenac potassium 25 mg tablets), and generic ibuprofen/famotidine tablets to the policy with associated criteria.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Added generic fenoprofen 400 mg capsules and generic diclofenac 2% solution to policy with criteria. Removed Qmiiz, Anaprox, Voltaren XR tablet, and profeno tablet from policy as they have been discontinued. Updated Single-Source Brand and Multi-Source Brand sections for the drugs that have become multi-source brands (Vivlodex, Zipsor, Naprelan 375 mg, Naprelan 500 mg, and Duexis).
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Simplified product list now that Naprelan (750 mg strength) is a Multi-Source brand with available generics.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Removed branded Diclofenac potassium 25 mg tablet from policy since it is now a generic agent. Added generic diclofenac potassium 25 mg tablets to the policy with associated criteria.

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Next Scheduled Review Date: 09/2024

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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