



Louisiana

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Policy # 00353

Original Effective Date: 06/25/2013

Current Effective Date: 09/19/2018

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.

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.

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[®] [celecoxib], Voltaren Gel[®] [diclofenac sodium], Motrin[®] [ibuprofen], Mobic[®] [meloxicam], Flector Patch[®] [diclofenac epolamine], Pennsaid[®] topical solution [diclofenac sodium], and Sprix[®] nasal spray [ketoralac])[‡] 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 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, Voltaren Gel, Pennsaid topical solution, Sprix nasal spray):
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**.**

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^{®‡} (fenoprofen) capsule, Fenoprofen capsule, Fenortho^{®‡} (fenoprofen) capsule, Vivlodex^{™‡} (meloxicam) capsule, Zorvolex^{™‡} (diclofenac) capsule, Zipsor^{®‡} (diclofenac potassium) capsule, Tivorbex^{™‡} (indomethacin) capsule, Indocin^{®‡} (indomethacin) suspension, Indocin^{™‡} (indomethacin) suppository, Naprelan^{®‡} (naproxen extended/controlled release) tablet, Naprosyn (naproxen) suspension, Duexis^{®‡} (ibuprofen/famotidine) tablet, Vimovo^{®‡} (naproxen/esomeprazole) tablet, Mobic (meloxicam) tablet, Voltaren XR^{®‡} (diclofenac) tablet, Celebrex (celecoxib) capsule, Lodine^{®‡} (etodolac) tablet, Feldene^{®‡} (piroxicam) capsule, Anaprox^{®‡} (naproxen) tablet, Anaprox DS^{®‡} (naproxen) tablet, Naprosyn^{®‡} (naproxen) tablet, EC-

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Naprosyn[®] (naproxen enteric[®] (diclofenac/sodium/misoprostol) tablet, and the following generic products: fenoprofen tablet, ketoprofen extended release capsule, mefenamic acid capsule, tolmetin capsule, tolmetin 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, diclofenac sodium tablet (enteric coated), diclofenac 24 hour release tablet, etodolac capsule/tablet (immediate release only), ketoprofen capsule (immediate release only), piroxicam capsule, indomethacin capsule (immediate release and sustained release), meclofenamate capsule, nabumetone tablet, naproxen tablet (immediate release), naproxen suspension, naproxen enteric coated tablet (delayed release, e.g., generic for EC-Naprosyn), sulindac tablet, ketorolac tablet, meloxicam tablet/suspension, flurbiprofen tablet, ibuprofen tablet/suspension, celecoxib capsule
Non-Select Generic NSAIDs: **PA required**	fenoprofen tablet, ketoprofen capsule (extended release), mefenamic acid capsule, tolmetin capsule, tolmetin 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)

- Nalfon capsule, Fenoprofen capsule, Fenortho capsule:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list.
- Vivlodex capsule:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be meloxicam tablets).
- Zorvolex capsule or Zipsor capsule:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be diclofenac

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potassium tablets, diclofenac sodium tablets [enteric coated], or diclofenac 24 hour release tablets).

- Tivorbex capsule, Indocin suspension:
 - Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be indomethacin capsules [immediate release or sustained release]).
- Naprelan tablet:
 - Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen immediate release or naproxen enteric coated [delayed release] tablets).
- Indocin suppository:
 - Patient can’t chew or swallow AND is currently NOT taking medications in tablet and/or capsule form.
- Duexis tablet:
 - Patient has tried and failed (e.g., intolerance of inadequate response) BOTH of the following after at least SIX months of combination therapy with each trial:
 - Prescription generic ibuprofen at a dosage of 800mg three times daily; AND prescription generic famotidine at a total daily dose of at least 40mg; 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.
- Vimovo tablet:
 - Patient has tried and failed (e.g., intolerance of 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 250mg, 375mg, or 500mg 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.

Non-Select Generics:

Note that products required to be tried and failed must be tried for at least ONE month each

- fenoprofen tablet, profeno tablet, mefenamic acid capsule, tolmetin capsule/tablet:
 - Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list.
- ketoprofen capsule (extended release):
 - Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be ketoprofen immediate release capsules).
- naproxen sodium extended release tablet (e.g., generic Naprelan):
 - Patient has tried and failed (e.g., intolerance of inadequate response) TWO generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen immediate release tablets or naproxen enteric coated delayed release tablets).

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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

- Mobic tablet:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be meloxicam tablets).
- Voltaren XR tablet:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be diclofenac 24 hour release tablets).
- Celebrex capsule:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be celecoxib capsules).
- Lodine tablet:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be etodolac capsule/tablets [immediate release]).
- Feldene capsule:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be piroxicam capsules).
- Anaprox, Anaprox DS, Naprosyn, EC-Naprosyn tablets:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen immediate release tablets or naproxen enteric coated delayed release tablets).
- Naprosyn suspension:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) THREE generic products from the “select generic” NSAID oral list (ONE of which MUST be naproxen suspension).
- Daypro tablet:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) TWO products from the “select generic” NSAID oral list; AND
 - o Patient has tried and failed (e.g., intolerance of inadequate response) generic oxaprozin tablets.
- Ponstel capsule:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) TWO products from the “select generic” NSAID oral list; AND

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- o Patient has tried and failed (e.g., intolerance of inadequate response) generic mefenamic acid capsules.
- Arthrotec tablet:
 - o Patient has tried and failed (e.g., intolerance of inadequate response) TWO products from the “select generic” NSAID oral list PLUS a trial and failure (e.g. intolerance of inadequate response) with TWO generic proton pump inhibitors and/or H2 blockers); AND
 - o Patient has tried and failed (e.g., intolerance of inadequate response) generic diclofenac/misoprostol.

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.****

Topical:

Based on review of available data, the Company may consider the following branded topical NSAIDs: Sprix[®] (ketorolac) nasal spray, Pennsaid (diclofenac) 2% solution, Flector (diclofenac) Patch, Voltaren (diclofenac) 1% gel 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	

Patient Selection Criteria

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

- Patient must meet the requirements of the requested drug:
 - o For Sprix nasal spray, Pennsaid 2% solution, Flector Patch, Voltaren 1% gel: Patient can't swallow AND the patient is NOT taking any other tablet/capsule products; OR
 - o For Pennsaid 2% solution, Flector 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
 - o For Pennsaid 2% solution, Flector 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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- o For Sprix nasal spray, Pennsaid 2% solution, Flector Patch:
 - Patient has tried and failed (e.g., intolerance of inadequate response) generic topical diclofenac 1.5% drops/klofenac for at least ONE month of therapy; AND
 - Patient has tried and failed (e.g., intolerance of inadequate response) generic diclofenac 1% gel for at least ONE month of therapy.
- o For Voltaren 1% gel:
 - Patient has tried and failed (e.g., intolerance of inadequate response) generic topical diclofenac 1.5% drops/klofenac for at least ONE month of therapy; AND
 - Patient has tried and failed (e.g., intolerance of 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 branded topical NSAID products when the patient selection criteria are not met to be **not medically necessary**.**

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 [no generic for 750mg]). The generic delayed release naproxen tablet is the generic for EC-Naprosyn (375mg and 500 mg).

Rationale/Source

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

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In regards 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.

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.

<p><u>Select Oral NSAIDs withOUT PA</u></p>	<p>diclofenac potassium tablet diclofenac sodium tablet (enteric coated) diclofenac 24 hour release tablet etodolac capsule/tablet (immediate release only) ketoprofen capsule (immediate release only) piroxicam capsule indomethacin capsule (immediate release and sustained release) meclofenamate capsule nabumetone tablet naproxen tablet (immediate release) naproxen suspension naproxen enteric coated delayed release tablet (generic EC-Naprosyn) sulindac tablet ketorolac tablet meloxicam tablet/suspension flurbiprofen tablet ibuprofen tablet/suspension celecoxib capsule</p>
<p><u>Select Topical NSAIDs withOUT PA</u></p>	<p>diclofenac 1.5% drops klofensaid 1.5% drops diclofenac 1% gel</p>

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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.

Next Scheduled Review Date: 09/2019

****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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