OVERVIEW
Nonsteroidal anti-inflammatory drugs (NSAIDs) exhibit anti-inflammatory, analgesic and antipyretic activities and are used for a variety of conditions. The mechanism of action of NSAIDs is related to prostaglandin synthetase inhibition. NSAIDs inhibit both cyclooxygenase (COX)-1, and COX-2 isoenzymes at therapeutic doses. In Arthrotec, diclofenac sodium is combined with misoprostol, a gastrointestinal (GI) mucosal protective prostaglandin E1 analog. The individual components of the combination products are available separately. Zorvolex (diclofenac capsules) and Vivlodex (meloxicam capsules) are not interchangeable with other diclofenac and meloxicam products.

POLICY STATEMENT
A preferred step therapy program has been developed to encourage the use of two preferred products prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of two preferred drugs within the 130-day look-back period are excluded from step therapy.

Preferred Medications
- diclofenac sodium (IR and ER)
- diclofenac potassium
- diclofenac sodium and misoprostol
- diclofenac sodium topical solution 1.5%*
- etodolac (IR and ER)
- flurbiprofen
- ibuprofen (IR and ER)
- indomethacin (IR and ER)
- ketoprofen (IR and ER)
- ketorolac [tablets]
- meclofenamate
- mefenamic acid
- meloxicam
- nabumetone
- naproxen
- naproxen sodium (IR and ER)
- oxaprozin
- piroxicam
- sulindac
- tolmetin

Non-Preferred Medication
- Anaprox, Anaprox DS
- Ansaid
- Arthrotec
- Cambia
- Feldene
- Indocin
- Klofensaid II 1.5%*
- Licart*
- Lodine
- Ponstel
- Qmiiz
- Tivorbex
- Vivlodex

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**Drug Policy**

<table>
<thead>
<tr>
<th>Cataflam</th>
<th>Mobic</th>
<th>Voltaren XR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daypro</td>
<td>Motrin</td>
<td>Voltaren gel 1%</td>
</tr>
<tr>
<td>Diclofenac sodium 1% topical gel*</td>
<td>Naprelan</td>
<td>Zipsor</td>
</tr>
<tr>
<td>Flector Patch*</td>
<td>Naprosyn, EC-Naprosyn</td>
<td>Zorvolex</td>
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</tbody>
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* Denotes topical product

**Preferred Step Therapy Criteria**

1. If the patient has tried two different prescription-strength generic preferred medications for the current condition, then authorization for a non-preferred branded medication may be given. Note: over-the-counter (OTC) NSAIDs count when the patient has used prescription-strength doses.

2. For patients who have difficulty swallowing or cannot swallow, authorization may be given for Pennsaid 2%, Flector patch, Klofensaid II, diclofenac sodium 1% topical gel, Licart topical system, or Voltaren gel if the patient has tried generic diclofenac sodium topical solution 1.5%.

3. For patients with a chronic musculoskeletal pain condition (e.g. OA) who will be applying Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, Licart topical system, or Voltaren gel to 3 or more joints/sites (hand, wrist, elbow, knee, ankle, or foot each count as one joint/site) who are at risk of NSAID-associated toxicity (e.g. patients with a previous GI bleed, history of peptic ulcer disease, impaired renal function, CV disease, hypertension, heart failure, elderly patients with impaired hepatic function or taking concomitant anticoagulants), authorization for Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, or Voltaren gel may be given if the patient has tried generic diclofenac sodium topical solution 1.5%. Significantly lower blood levels are achieved with the topical NSAIDs compared to the oral NSAIDs.

4. For patients 75 years of age or older with hand or knee OA, authorization may be given for Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, Licart topical system, or Voltaren gel if the patient has tried generic diclofenac sodium topical solution 1.5%. The ACR OA guidelines state that in patients 75 years of age or older, topical NSAIDs are preferred over oral NSAIDs for hand and knee OA.

**Approval Duration:** 365 days (1 year)

**Step Therapy Exception Criteria**

Approve for 1 year if the patient meets the following (A, B, or C):
A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics [documentation required]; OR

B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent [documentation required]; OR

C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:

1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period; OR
2. When 130 days of the patient’s prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent); OR
3. There are no generic alternatives to the requested non-preferred agent [NOTE: ESI reviewer to list generic alternatives for requested non-preferred medication and confirm accuracy of physician response]

**Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

**Approval Duration:** All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

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**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**REFERENCES**

5. Flector® Patch [prescribing information]. Bristol, TN: King Pharmaceuticals; August 2011.
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33.Pennsaid® 1.5% topical solution [prescribing information]. Hazelwood, MO: Mallinckrodt; October 2013.
35. Dyloject” injection for intravenous use [prescribing information]. Lake Forest, IL: Hospira; December 2014.
36. Diclofenac sodium 1.5% topical solution [prescribing information]. Madison, MS: Circle Laboratories; March 2016.