Medical Mutual®

Branded Nonsteroidal Anti-Inflammatory Drug (NSAID)
Preferred Step Therapy Policy
July 2016

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. In Vimovo™, naproxen is combined with esomeprazole magnesium (Nexium®), a PPI. In Duexis®, ibuprofen is combined with famotidine, a histamine H₂-receptor antagonist (H₂RA). The individual components of the combination products are available separately. Zorvolex™ (diclofenac capsules) and Vivlodex™ (meloxicam capsules) and are not interchangeable with other diclofenac and meloxicam products.

POLICY STATEMENT
A step therapy program has been developed to encourage the use of two generic Step 1a products prior to the use of a Step 2a product (Vimovo and Duexis not included). For Vimovo (Step 2b), patients are required to try one prescription naproxen product (Step 1b) and one prescription proton pump inhibitor product (PPI) [Step 1b] prior to Vimovo. For Duexis (Step 2c), patients are required to try one prescription oral ibuprofen product (Step 1c) product and one prescription oral histamine H₂-receptor antagonist (H₂RA) [Step 1c]. If the step therapy rule is not met for a Step 2 agent (a, b or c) at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration.

AUTOMATION: Patients with a history of two Step 1a drugs within the 130-day look-back period are excluded from step therapy (note: Vimovo and Duexis are not included in this Step). For Vimovo (Step 2b), patients with a history of both one prescription PPI and one naproxen product within the 130-day look-back period are excluded from step therapy. For Duexis (Step 2c), patients with a history of both one prescription H₂RA and one prescription oral ibuprofen product within the 130-day look-back period are excluded from step therapy.

Generic NSAIDs

**Step 1a NSAIDs (generic):**
- diclofenac sodium (IR and ER)
- diclofenac potassium
- diclofenac sodium and misoprostol
- diclofenac sodium topical solution 1.5% *
- etodolac (IR and ER)
- fenoprofen
- flurbiprofen

**Step 2a NSAID (brand):**
- Anaprox, Anaprox DS
- Feldene
- Ponstel

**Step 2a NSAID (brand):**
- ibuprofen
- indomethacin (IR and ER)
- ketoprofen (IR and ER)
- ketorolac [tablets]
- meclofenamate
- meloxicam
- nabumetone
- naproxen
- naproxen sodium (IR and ER)
- oxaprozin
- piroxicam
- sulindac
- tolmetin sodium
Ansaid  |  Indocin  |  Sprix  
Arthrotec  |  Klofensaid II  |  Tivorbex  
Cambia  |  Mobic  |  Vivlodex  
Cataflam  |  Motrin  |  Voltaren XR  
Daypro  |  Nalfon  |  Voltaren Gel  
Diclofenac sodium 1% topical gel  |  Naprelan  |  Zipsor  
Fenoprofen 400 mg (brand)  |  Naprosyn, EC-Naprosyn  |  Zorvolex  
Flector Patch*  |  Pennsaid 1.5% and 2%*  

* Denotes topical product

Vimovo

**Step 1b (brand or generic):**
- Prescription naproxen sodium
- Prescription naproxen
- Prescription dexlansoprazole
- Prescription omeprazole magnesium
- Prescription esomeprazole magnesium
- Prescription omeprazole/sodium bicarbonate
- Prescription esomeprazole strontium
- Prescription pantoprazole (oral)
- Prescription lansoprazole
- Prescription omeprazole

**Step 2b NSAID:**
- Vimovo

Duexis

**Step 1c (brand or generic):**
- Prescription ibuprofen (oral)
- Prescription cimetidine (oral)
- Prescription nizatidine (oral)
- Prescription famotidine (oral)
- Prescription ranitidine (oral)

**Step 2c NSAID:**
- Duexis

**CRITERIA**

**Generic NSAIDs**

1. If a patient has tried two unique generic prescription-strength NSAIDs for the current condition, then authorization for a brand name NSAID may be given. Note: Over-the-counter (OTC) NSAIDs count as alternatives when the patient used prescription-strength doses.

2. For patients who have difficulty swallowing or cannot swallow, authorization may be given for Sprix, Pennsaid 2%, Flector Patch, Klofensaid II, diclofenac sodium 1% topical gel, 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, or Voltaren Gel to ≤ 3 joints/sites (i.e., 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 with hand or knee OA, authorization may be given for Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, or Voltaren Gel if the patient has tried generic diclofenac sodium topical solution 1.5%. The 2012 ACR OA guidelines state that in patients ≥ 75 years of age, topical NSAIDs are preferred over oral NSAIDs for hand and knee OA.

**Vimovo**

1. Coverage of Vimovo is recommended if the patient has tried both one prescription proton pump inhibitor (PPI) [e.g., omeprazole, lansoprazole, pantoprazole] and one prescription naproxen product (brand or generic). Coverage of Vimovo is not recommended if the patient has only tried OTC naproxen, other NSAIDs besides naproxen, a COX-2 inhibitor (Celebrex), or OTC PPIs.

**Duexis**

1. Coverage of Duexis is recommended if the patient has tried both one prescription histamine-2 receptor antagonist (H2RA) [e.g., famotidine, ranitidine, nizatidine] and one prescription ibuprofen product (brand or generic). Coverage of Duexis is not recommended if the patient has only tried OTC ibuprofen, other NSAIDs besides ibuprofen, a COX-2 inhibitor (Celebrex), or OTC H2RAs.

**References**

- Duexis® tablets [prescribing information]. Deerfield, IL: Horizon Pharma; November 2012.
- Flector® Patch [prescribing information]. Bristol, TN: King Pharmaceuticals; August 2011.


Nabumetone tablets [prescribing information]. Morgantown, WV; Mylan; July 2012.


Pennsaid® 1.5% topical solution [prescribing information]. Hazelwood, MO: Mallinckrodt; October 2013.


Dyloject® injection for intravenous use [prescribing information]. Lake Forest, IL: Hospira; December 2014.

Diclofenac sodium 1.5% topical solution [prescribing information]. Madison, MS: Circle Laboratories; March 2014.

Diclofenac sodium 1% topical gel [prescribing information]. Piscataway, NJ and Glasgow KY: Amneal Pharmaceuticals; December 2015.

Klofensaid II topical solution 1.5% [prescribing information]. Buena, NJ and San Fernando, CA: IGI Laboratories and PureTek Corporation; March 2016.

**OTHER REFERENCES UTILIZED**


• Roth SH, Fuller P. Pooled safety analysis of diclofenac sodium topical solution 1.5% (w/w) in the treatment of osteoarthritis in patients aged 75 years or older. *Clin Interv Aging.* 2012;7:127-137.