

# Pharmacy Management Drug Policy

**SUBJECT: Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)**

**POLICY NUMBER: PHARMACY-30**

**EFFECTIVE DATE: 8/00**

**LAST REVIEW DATE: 3/5/2020**

*If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.*

## **DESCRIPTION:**

Due to the increased utilization of brand Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), especially as first line therapy for pain management, a Prior Authorization program has been implemented. It is well documented that no NSAID is consistently more effective than any other (The Medical Letter Vol. 42, July 10, 2000). For this reason, the criteria applied through the Prior Authorization program will promote efficacy and value to members by emphasizing utilization of OTC and generic NSAIDS at prescription strength as first line therapy for acute and chronic pain management in situations where GI bleed risk is minimal.

## **Black Box Warning:**

All NSAIDS are required to have a Black Box Warning in their labeling regarding the cardiovascular & gastrointestinal risks associated with their use.

## **DRUG SPECIFIC POLICIES/CRITERIA:**

### **Duexis - ibuprofen/famotidine**

1. Must have a diagnosis of Osteoarthritis or Rheumatoid Arthritis
2. Based on comparable indications, efficacy, safety profiles, and similar strengths of generic ibuprofen and famotidine, the member will be required to use generic ibuprofen and famotidine

### **Fenoprofen tablets**

1. Must have a diagnosis of Osteoarthritis or Rheumatoid Arthritis
2. Must have tried 3 different generic oral NSAIDs
3. All other indications are considered not medically necessary due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results.

### **Flector and generic diclofenac patches**

1. Must have a diagnosis of Acute Pain related to minor strains, sprains, and bruises
2. Must have documentation of a contraindication to oral NSAIDs
3. Approval will be for 3 months, to allow short term use.
4. Quantity limit of 60 patches/30 days

## Pharmacy Management Drug Policy

### NSAIDS COX 2

#### **Indomethacin 20 mg capsules and Indomethacin 50 mg suppositories**

1. Must have a diagnosis of ankylosing spondylitis, gouty arthritis, osteoarthritis, or rheumatoid arthritis
2. Must have had serious side effects or drug failure with another version of indomethacin and 2 other oral NSAIDs
3. Alternatives for indomethacin suppositories for patients who cannot swallow solid oral dosage forms include ibuprofen suspension and meloxicam suspension

#### **Ketoprofen 25 mg capsules**

1. Must have a diagnosis of osteoarthritis, rheumatoid arthritis, or primary dysmenorrhea
2. Must have had serious side effects or drug failure with a different strength of ketoprofen and two other generic oral NSAIDs

#### **Naprelan, generic Naproxen ER, and naproxen suspension**

1. Must have had serious side effects or drug failure with immediate release naproxen tablets and two other generic oral NSAIDs
2. Alternatives for naproxen suspension for patients who cannot swallow solid oral dosage forms include ibuprofen suspension and meloxicam suspension

#### **Pennsaid – diclofenac 2% solution**

1. Must have a diagnosis of Osteoarthritis of the knee, **AND**
2. Patient must have had a trial of TWO (2) generic oral NSAIDs, **AND** topical diclofenac (Voltaren) 1% gel.
3. For patients age 65 and older, only a trial of topical diclofenac (Voltaren) 1% gel is required.

#### **Qmiiz – meloxicam ODT**

1. Member must have a diagnosis of Osteoarthritis, Rheumatoid Arthritis, or Juvenile Rheumatoid Arthritis
  - a) For the diagnosis of juvenile rheumatoid arthritis, the member must weigh at least 60 kg
2. Must have had serious side effects or drug failure with celecoxib capsules (may be opened and sprinkled over applesauce)
3. Must be unable to swallow generic meloxicam tablets due to a swallowing disorder that has been confirmed by a speech and swallow evaluation

#### **Relafen DS – nabumetone tablets**

1. Must have serious side effects or drug failure with generic nabumetone and two other generic oral NSAIDs
2. Quantity limit of 60 tablets per 30 days

## Pharmacy Management Drug Policy

### NSAIDS COX 2

#### **Sprix and generic ketorolac/tromethamine nasal spray**

1. For a diagnosis of headaches/migraines there must be a previous trial of at least one non oral (injection or nasal spray) triptan and one other acute therapy with different mechanism of action (NSAID, DHEA, etc)
2. For a diagnosis of general acute pain (ex. Post op pain) Sprix will only be authorized for those individuals unable to tolerate oral medications (such as oral ketorolac). Approvals for acute pain will only be for 3 months.
3. Quantity limit of 5 bottles per 30 days

#### **Tivorbex – indomethacin**

1. Must have a diagnosis of Acute Pain **AND**
2. Must have documentation of a trial of a higher strength (minimum 50mg) of generic indomethacin, which led to intolerance.
3. Approval will be for 1 month, to afford short term use.
4. Quantity limit of 90 capsules / 30 days.

#### **Vimovo – naproxen/esomeprazole**

1. Must have a diagnosis of Osteoarthritis, Rheumatoid Arthritis, or Ankylosing Spondylitis
2. Must have documentation of being at high risk for gastric ulcer.
  - Risk factors include: Patient greater than 65 years of age, previous history of peptic ulcer disease
3. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic naproxen and esomeprazole, the member will be required to use generic naproxen and esomeprazole unless there is adequate justification as to why these are not appropriate.

#### **Vivlodex – meloxicam**

1. Must have a diagnosis of Osteoarthritis **AND**
2. Must have had a trial of 3 different, generic oral or topical NSAIDs, one of which is meloxicam.
3. For patients age 65 and older, **only** a trial of topical diclofenac (Voltaren) 1% gel is required.
4. Quantity limit is 30 capsules / 30 days.

#### **Zipsor – diclofenac**

1. Must have a diagnosis of acute pain **AND**
2. Must have documentation of a trial of a higher strength (minimum 50mg) of oral generic diclofenac, which led to intolerance.
3. Approval will be for 1 month, to afford short term use.

#### **Zorvolex – diclofenac**

1. Must have a diagnosis of Osteoarthritis **AND**
2. Must have had a trial of 3 different, generic oral or topical NSAIDs, one of which is oral diclofenac.
3. For patients age 65 and older, only a trial of topical diclofenac 1% (Voltaren) gel is required

## Pharmacy Management Drug Policy

### NSAIDS COX 2

#### **POLICY GUIDELINES:**

1. Mild GI upset is a therapeutic class side effect for NSAIDS and COX-2 inhibitors and therefore does not provide medical necessity for an exception.
2. The long-term continuous use of all NSAIDS, except for aspirin may increase the risk of heart attack or stroke.
3. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
4. Unless otherwise stated above within the individual drug criteria, approval time period will be for 2 years.
  - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
5. Prior-authorization is contract dependent.
6. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
  - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
  - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
  - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
  - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
  - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rationale for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
  - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
  - This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.

## Pharmacy Management Drug Policy

### NSAIDS COX 2

#### **UPDATES:**

<b>Date:</b>	<b>Revision:</b>
3/20	Revised
12/19	Revised
11/19	P&T Approval
10/19	Revised
8/19	Reviewed
5/19	Revised
4/19	Revised
9/18	Revised
7/18	Revised
1/17	Reviewed
3/16	Reviewed

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