# Pharmacy Management Drug Policy

**SUBJECT: Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)**
**POLICY NUMBER: PHARMACY-30**
**EFFECTIVE DATE: 08/2000**
**LAST REVIEW DATE: 8/24/2023**

*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. This drug policy applies to the following line/s of business:*

| **Policy Application** | | |
|---|---|---|
| **Category**: | ☒ Commercial Group (e.g., EPO, HMO, POS, PPO) | ☐ Medicare Advantage |
| | ☒ On Exchange Qualified Health Plans (QHP) | ☐ Medicare Part D |
| | ☒ Off Exchange Direct Pay | ☒ Essential Plan (EP) |
| | ☐ Medicaid & Health and Recovery Plans (MMC/HARP) | ☐ Child Health Plus (CHP) |
| | ☐ Federal Employee Program (FEP) | ☐ Ancillary Services |
| | ☐ Dual Eligible Special Needs Plan (D-SNP) | |

## 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 and ibuprofen/famotidine tablets |
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| 1. Must have a diagnosis of osteoarthritis or rheumatoid arthritis<br>2. Must have documentation of being at high risk for gastric ulcers.<br>• Risk factors include: Patient greater than 65 years of age, previous history of peptic ulcer disease<br>3. Must have had serious side effects or drug failure to 3 different PPIs with each PPI trial used in combination with ibuprofen 800 mg<br>4. 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 unless there is adequate justification as to why these are not appropriate<br>5. In addition, coverage of brand name Duexis will require serious side effects or drug failure to ibuprofen/famotidine tablets (generic for Duexis) |

| Fenortho, Nalfon, fenoprofen capsules and fenoprofen tablets |
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| 1. Must have a diagnosis of osteoarthritis or rheumatoid arthritis<br>2. Must have tried 3 different generic oral NSAIDs<br>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, Licart and generic diclofenac patches |
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| 1. Must have a diagnosis of acute pain related to minor strains, sprains, and bruises<br>2. Must have documentation of a contraindication to oral NSAIDs<br>3. Approval will be for 3 months, to allow short term use.<br>4. Quantity limit:<br>a. 60 patches/30 days for Flector and generic diclofenac patches<br>b. 30 patches/30 days for Licart |

| Lofena and diclofenac potassium 25 mg tablets |
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| 1. Must have a documented diagnosis of primary dysmenorrhea, mild to moderate pain, osteoarthritis, or rheumatoid arthritis<br>2. Must have had a documented trial of 3 different, generic oral NSAIDs, one of which is oral diclofenac tablets dosed at a higher strength (minimum 50 mg) which led to intolerance<br>3. Approval for acute pain will be for 1 month, to afford short term use. Approval for chronic pain conditions will be for 2 years.<br>4. Quantity Limit: 90 tablets/30 days |

## Indocin and indomethacin 50 mg rectal 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 formulation of indomethacin and 2 other oral NSAIDs
3. If the patient is unable to swallow solid oral dosage forms, ibuprofen suspension must be tried with serious side effects or drug failure

## 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, Naprosyn suspension, 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
3. Brand Naprelan will also require documentation of serious side effects or drug failure to naproxen ER (generic Naprelan)
4. Brand Naprosyn suspension will also require documentation of serious side effects or drug failure to naproxen suspension (generic Naprosyn)

## Pennsaid and 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 1% gel and diclofenac 1.5% solution
3. For patients aged 65 and older, only a trial of topical diclofenac 1% gel and diclofenac 1.5% solution is required.
4. Quantity limit of 1 bottle per month
   a. Additional quantities will be granted based on FDA-approved dosing

## Qmiiz (meloxicam ODT) and meloxicam oral suspension

1. Must have a diagnosis of osteoarthritis, rheumatoid arthritis, or juvenile rheumatoid arthritis
   a. Requests will not be approved for any other indication
2. Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the member will be required to use generic meloxicam tablets unless there is adequate justification as to why this formulation is not appropriate **AND**
3. If unable to use generic meloxicam tablets, the member must try and failed or have severe intolerance to all lower cost generic alternatives such as ibuprofen, naproxen, celecoxib, diclofenac, etodolac, fenoprofen, flurbiprofen, indomethacin, ketoprofen, and nabumetone.

## 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

## Seglentis – celecoxib and tramadol tablets

1. The health plan has determined that Seglentis is not medically necessary due to the availability of other opioid and NSAID medications with similar indications and safety profiles that are likely to produce equal therapeutic results when used in combination
2. Quantity limit of 120 tablets per 30 days

## Sprix and 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 and indomethacin 20 mg capsules

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 and naproxen/esomeprazole tablets

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. Must have had serious side effects or drug failure to 3 different PPIs with each PPI trial used in combination with naproxen
4. 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 and meloxicam capsules

1. Must have a diagnosis of osteoarthritis **AND**
2. Must have documentation of serious side effects or drug failure to 3 different generic oral NSAIDs, one of which is meloxicam tablets
3. In addition, coverage of brand name Vivlodex capsules will require serious side effects or drug failure to generic meloxicam capsules (generic Vivlodex)
4. Quantity limit is 30 capsules / 30 days

## Zipsor and diclofenac potassium 25 mg capsules

1. Must have a diagnosis of acute pain **AND**
2. Must have documentation of a trial of a higher strength (minimum 50 mg) of oral generic diclofenac, which led to intolerance
3. Approval will be for 1 month, to afford short term use
4. Quantity limit is 120 capsules per 30 days

| Zorvolex and diclofenac 35 mg capsules |
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| 1. Must have a diagnosis of osteoarthritis **AND**<br>2. Must have had a trial of 3 different, generic oral NSAIDs, one of which is oral diclofenac tablets dosed at a higher strength (minimum 50 mg) which led to intolerance **OR**<br>3. Must have a diagnosis of mild to moderate acute pain **AND**<br>4. Must have had a trial of 3 different, generic oral NSAIDs, one of which is oral diclofenac tablets dosed at a higher strength (minimum 50 mg) which led to intolerance **AND**<br>5. Approval for acute pain will be for 1 month, to afford short term use. |

**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. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.
5. 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.
6. Prior-authorization is contract dependent.
7. 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 rational 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.

**UPDATES:**

| Date: | Revision: |
|---|---|
| 8/23 | Revised/P&T Committee Approval |
| 12/22 | Revised |
| 8/22 | Revised |
| 7/22 | P&T Committee Approval |
| 6/22 | Revised |
| 5/22 | Revised |
| 3/22 | Revised |
| 2/22 | Revised |
| 11/21 | Revised |
| 10/21 | Revised |
| 9/21 | Revised |
| 8/21 | Revised |
| 7/21 | P&T Committee Approval |
| 6/21 | Revised |
| 3/21 | Revised |
| 1/21 | Revised |
| 9/20 | Revised and P&T Committee Approval |
| 3/20 | Revised |
| 12/19 | Revised |
| 11/19 | P&T Committee 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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