



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	NSAIDs PDL Edit
<b>First Implementation Date:</b>	June 25, 2012
<b>Revised Date:</b>	April 6, 2023
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly used to treat rheumatoid arthritis (RA), osteoarthritis (OA), and pain from various etiologies. NSAIDs are the most widely used drugs in the United States, with approximately 80 million prescriptions being filled yearly. These drugs, however, are associated with adverse events including gastrointestinal bleeding, peptic ulcer disease, hypertension, edema, renal disease, and increased risk of myocardial infarction.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Celecoxib</li> <li>• Diclofenac 1% Gel OTC</li> <li>• Diclofenac Sodium DR/EC Tabs</li> <li>• Ibuprofen</li> <li>• Ketorolac Inj/Tabs</li> <li>• Meloxicam Tabs</li> <li>• Naproxen OTC</li> <li>• Naproxen Tabs Rx (gen Naprosyn®)</li> </ul>	<ul style="list-style-type: none"> <li>• Arthrotec®</li> <li>• Celebrex®</li> <li>• Daypro®</li> <li>• Diclofenac 1% Gel Rx</li> <li>• Diclofenac 1.3% Patch (gen Flector®)</li> <li>• Diclofenac Topical Soln</li> <li>• Diclofenac Caps (gen Zorvolex®)</li> <li>• Diclofenac Potassium</li> <li>• Diclofenac Sodium ER (gen Voltaren® XR)</li> <li>• Diclofenac/Misoprostol</li> <li>• Diflunisal</li> <li>• Duexis®</li> <li>• Elyxyb</li> <li>• Etodolac</li> <li>• Etodolac ER</li> <li>• Feldene®</li> <li>• Fenoprofen</li> <li>• Flector® Patch</li> <li>• Flurbiprofen</li> <li>• Ibuprofen/Famotidine</li> <li>• Indocin®</li> </ul>

	<ul style="list-style-type: none"> <li>• Indomethacin</li> <li>• Indomethacin ER</li> <li>• Ketoprofen</li> <li>• Ketoprofen ER</li> <li>• Ketorolac Nasal Spray</li> <li>• Licart™</li> <li>• <b>Lofena™</b></li> <li>• Meclofenamate</li> <li>• Mefenamic Acid</li> <li>• Meloxicam Caps</li> <li>• Mobic®</li> <li>• Nabumetone</li> <li>• Nalfon®</li> <li>• Naprelan®</li> <li>• Naprosyn®</li> <li>• Naproxen CR (gen Naprelan®)</li> <li>• Naproxen DS (gen Anaprox® DS)</li> <li>• Naproxen EC (gen Naprosyn® EC)</li> <li>• Naproxen Sodium (gen Anaprox®)</li> <li>• Naproxen Susp</li> <li>• Naproxen/Esomeprazole</li> <li>• Oxaprozin</li> <li>• Pennsaid®</li> <li>• Piroxicam</li> <li>• Relafen® DS</li> <li>• Sulindac</li> <li>• Tolmetin</li> <li>• Vimovo®</li> <li>• Voltaren®</li> </ul>
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Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: NSAIDs
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- For non-preferred agents:
  - For diclofenac epolamine 1.3% patch:
    - ~~Documented diagnosis of acute pain due to minor strains, sprains or contusions in the last 30 days AND~~
    - Failure to achieve desired therapeutic outcomes with a trial on 2 or more preferred oral agents
      - Documented trial period for preferred agents **OR**
      - Documented ADE/ADR to preferred agents (gastrointestinal effects, high risk for congestive heart failure, renal failure, concomitant use of lithium) **OR**
  - Failure to achieve desired therapeutic outcomes with a trial on 4 or more preferred agents

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- Documented trial period for preferred agents **OR**
- Documented ADE/ADR to preferred agents **AND**
- ~~For Cambia: documented diagnosis of acute migraine~~
- For diclofenac sodium solution: documented diagnosis of osteoarthritis of knee
- **For Elyxyb: Clinical Consultant Review for medical necessity**
- For Vimovo: documented compliance on naproxen and omeprazole single agents (30/180 days)

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
CELEBREX 50 MG CAP	CELECOXIB	2 capsules per day
CELEBREX 100 MG CAP	CELECOXIB	2 capsules per day
CELEBREX 200 MG CAP	CELECOXIB	2 capsules per day
CELEBREX 400 MG CAP	CELECOXIB	1 capsule per day
FLECTOR 1.3% PATCH	DICLOFENAC EPOLAMINE	2 patches per day
RELAFEN 500 MG TAB	NABUMETONE	4 tablets per day
RELAFEN 750 MG TAB	NABUMETONE	2 tablets per day
RELAFEN DS 1,000 MG TAB	NABUMETONE	2 tablets per day
SPRIX NASAL SPRAY	KETOROLAC	1 bottle per day AND 5 bottles per month
TORADOL 10 MG TAB	KETOROLAC	4 tablets per day AND 20 tablets per month
VOLTAREN 1% GEL	DICLOFENAC SODIUM	17 grams per day

## Required Documentation

Laboratory Results:       Progress Notes:

MedWatch Form:       Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

3 months

## References

- Evidence-Based Medicine and Fiscal Analysis: "NSAIDs – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: "Non-steroidal anti-inflammatory drugs (NSAIDs)", UMKC-DIC; August 2022.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-line; 2022.