

SmartPA Criteria Proposal

Drug/Drug Class:	NSAID Agents PDL Edit
First Implementation Date:	June 25, 2012
Proposed Date:	December 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<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"> • Celecoxib • Diclofenac 1% Gel OTC • Diclofenac Sodium DR/EC Tabs • Ibuprofen • Ketorolac Inj/Tabs • Meloxicam • Naproxen OTC • Naproxen Tabs Rx (gen Naprosyn[®]) 	<ul style="list-style-type: none"> • Arthrotec[®] • Cambia[®] • Celebrex[®] • Daypro[®] • Diclofenac 1% Gel Rx • Diclofenac 1.3% Patch (gen Flector[®]) • Diclofenac 1.5% Topical Soln • Diclofenac Caps (gen Zorvolex[®]) • Diclofenac Potassium • Diclofenac Sodium ER (gen Voltaren[®] XR) • Diclofenac/Misoprostol • Diflunisal • Duexis[®] • Etodolac • Etodolac ER • Feldene[®] • Fenoprofen • Flector[®] Patch • Flurbiprofen • Indocin[®] • Indomethacin

	<ul style="list-style-type: none"> • Indomethacin ER • Ketoprofen • Ketoprofen ER • Ketorolac Nasal Spray • Licart™ • Meclofenamate • Mefenamic Acid • Mobic® • Nabumetone • Nalfon® • Naprelan® • Naprosyn® • Naproxen CR (gen Naprelan®) • Naproxen DS (gen Anaprox® DS) • Naproxen EC (gen Naprosyn® EC) • Naproxen Sodium (gen Anaprox®) • Naproxen Susp • Naproxen/Esomeprazole • Oxaprozin • Pennsaid® • Piroxicam • Qmiiiz™ ODT • Relafen™ DS • Sprix® • Sulindac • Tivorbex® • Tolmetin • Vimovo® • Vivlodex® • Voltaren® 1% Gel • Zipsor® • Zorvolex®
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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: NSAID Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with a trial on 4 or more preferred agents
 - Documented trial period for preferred agents **OR**

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- Documented ADE/ADR to preferred agents **AND**
- For Vimovo: documented compliance on naproxen and omeprazole single agents (30/180 days)
- For Cambia: documented diagnosis of acute migraine in the last 2 years
- For Diclofenac sodium solution: documented diagnosis of osteoarthritis of knee in the last 2 years
- For Flector 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 (GI effects; high risk for CHF, renal failure, concomitant use of lithium)

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
Flector 1.3% Patch	Diclofenac Epolamine	2 patches per day
Relafen 500 mg	Nabumetone	4 tablets per day
Relafen 750 mg	Nabumetone	2 tablets per day
Relafen DS 1,000 mg	Nabumetone	2 tablets per day
Sprix Nasal Spray	Ketorolac	1 bottle per day AND 5 bottles per month
Toradol 10mg tablet	Ketorolac	5 tablets per day AND 25 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

1 year

References

1. Drug Effectiveness Review Project – Drug Class Review on "COX-2 Inhibitors and Non-steroidal Anti-inflammatory Drugs (NSAIDs)." Center for Evidence-Based Policy, Oregon Health & Science University; November 2006; Updated November 2010; Evidence Scan Update, December 2015.
2. Evidence-Based Medicine and Fiscal Analysis: "NSAIDs – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; October 2020.

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3. Evidence-Based Medicine Analysis: “Non-steroidal anti-inflammatory drugs (NSAIDs)”, UMKC-DIC; September 2020.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2019.
5. USPDI, Micromedex; 2020.
6. Drug Facts and Comparisons On-line; 2020.

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