

5.70.026

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2023
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	June 20, 2013
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**Last Review Date:** March 10, 2023

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## Anti-Inflammatory Pain Powders

### Description

Celecoxib Powder, Diclofenac Powder, Fenoprofen Powder, Flurbiprofen Powder, Ibuprofen Powder, Ketoprofen Powder, Meloxicam Powder, Naproxen Powder, Tramadol Powder

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### Background

Pharmacy compounding is an ancient practice in which pharmacists combine, mix or alter ingredients to create unique medications that meet specific needs of individual patients. Some examples of the need for compounding products would be: the dosage formulation must be changed to allow a person with dysphagia (trouble swallowing) to have a liquid formulation of a commercially available tablet only product, or to obtain the exact strength needed of the active ingredient, to avoid ingredients that a particular patient has an allergy to, or simply to add flavoring to medication to make it more palatable.

Celecoxib, diclofenac, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, meloxicam, and naproxen are non-steroidal anti-inflammatory drugs (NSAID) that decrease inflammation, pain and fever by inhibiting COX-1 and 2 enzymes, which then inhibit the production of prostaglandins and leukotrienes (1-7). Tramadol is a centrally acting synthetic opioid analgesic used to treat moderate to moderately severe chronic pain in adults. Tramadol has been shown to inhibit reuptake of norepinephrine and serotonin, as have some other opioid analgesics (8).

### Regulatory Status

FDA-approved indications:

1. Celecoxib is FDA approved in an oral formulation for osteoarthritis (OA), rheumatoid

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- arthritis (RA), juvenile rheumatoid arthritis (JRA) in patients 2 years and older, ankylosing spondylitis (AS), acute pain (AP), primary dysmenorrhea (PD) (1).
2. Diclofenac is FDA approved in oral formulations for osteoarthritis (OA), rheumatoid arthritis (RA), and ankylosing spondylitis (2).
  3. Fenoprofen is FDA approved in an oral formulation for the relief of mild to moderate pain in adults and for the relief of the signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA) (3).
  4. Flurbiprofen is FDA approved in an oral formulation for the relief of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA) (4). Flurbiprofen ophthalmic solution is indicated for the inhibition of intraoperative miosis (5).
  5. Ibuprofen is FDA approved in an oral formulation for osteoarthritis (OA), rheumatoid arthritis (RA), mild to moderate pain and primary dysmenorrhea (5).
  6. Ketoprofen is FDA-approved in an oral formulation for the treatment of osteoarthritis, pain management, primary dysmenorrhea and rheumatoid arthritis (7).
  7. Meloxicam is FDA approved in an oral formulation for osteoarthritis (OA), rheumatoid arthritis (RA), juvenile rheumatoid arthritis (JRA) in patients 2 years and older (8).
  8. Naproxen is FDA approved in an oral formulation for the relief of minor aches and pains and for the temporary reduction of fever (9).
  9. Tramadol is FDA approved in an oral formulation for the management of moderate to moderately severe pain in adults (10).

All NSAIDs carry a boxed warning for cardiovascular risk. Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction and stroke. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (1-9).

The boxed warning also includes GI risk. NSAIDs cause an increased risk of serious GI adverse reactions including bleeding, ulceration and perforation of the stomach or intestines. These reactions can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI reactions (1-9).

Possible illegal or illicit use should be considered when prescribing or dispensing Ultram in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. Misuse or abuse poses a significant risk to the patient that could result in overdose and death. Tramadol should be used in caution with patients with respiratory depression, head trauma, and when used in conjunction with alcohol or other drugs that cause central nervous system depression (10).

Off-Label Uses:

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Celecoxib, diclofenac, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, meloxicam, naproxen, and tramadol compounded topical preparations have not been shown to be superior to commercially available topical diclofenac preparations.

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Celecoxib, diclofenac, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, meloxicam, naproxen, and tramadol powder may be considered **medically necessary** in for patients if the compounded product is being used for an FDA-approved indication, the requested dosage form is for oral use or ophthalmic use; the requested dose/ strength does **NOT** exceed the maximum FDA- approved dose/strength for the requested ingredient; the requested dose is not commercially available; the requested dosage form is not being used topically except for diclofenac.

Celecoxib, diclofenac, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, meloxicam, naproxen, and tramadol powder may be considered **investigational** in diagnoses that are off-label or in formulations that do not have a confirmed FDA approval of use.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

FDA-approved indication supporting the use of the compounded ingredient for the diagnosis provided

**AND ALL** of the following:

1. The requested dosage form is for oral use or ophthalmic use
2. The requested dose/ strength does **NOT** exceed the maximum FDA- approved dose/strength for the requested ingredient
3. The requested dose is **NOT** commercially available
4. The requested dosage form is not being used topically except for Diclofenac

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## **Prior – Approval *Renewal* Requirements**

Same as above

### [Policy Guidelines](#)

## **Pre - PA Allowance**

None

## **Prior - Approval Limits**

**Duration** 12 months

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## **Prior – Approval *Renewal* Limits**

Same as above

### [Rationale](#)

#### **Summary**

Compounded drug products may be considered medically necessary if the compounded product is being used for an FDA-approved indication, the formulation requested is an FDA-approved formulation; the strength requested is not available commercially and does not exceed the maximum FDA-approved strength of the product; and is not being used for cosmetic or erectile dysfunction purposes (1-10).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of celecoxib, diclofenac, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, meloxicam, naproxen, and tramadol powder while maintaining optimal therapeutic outcomes.

#### **References**

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3. Fenoprofen [package insert]. Largo, FL: Belcher Pharmaceuticals, LLC; April 2017.
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7. Ketoprofen [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; July 2015.
8. Mobic [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2016.
9. Aleve [package insert]. Whippany, NJ: Bayer HealthCare LLC; July 2017.
10. Ultram [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.

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## Policy History

Date	Action
May 2015	Revised flurbiprofen powder to include celecoxib, ibuprofen, ketoprofen, meloxicam and tramadol powder. 5.02.26 Flurbiprofen powder was add on PA June 2013 5.02.29 Celecoxib powder was add on PA September 2013 5.02.27 Ketoprofen powder was add on PA June 2013
June 2015	Annual editorial review and reference update
November 2015	Addition of diclofenac powder
December 2015	Annual review
March 2016	Annual editorial review Addition of the diclofenac exception on topical products Policy number changed from 5.02.26 to 5.70.26
March 2017	Annual editorial review and reference update
March 2018	Annual editorial review and reference update
March 2019	Addition of fenoprofen powder and naproxen powder
June 2019	Annual review
March 2020	Annual review
March 2021	Annual review
March 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.70.026

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.**