# Clinical Policy: Diclofenac (Pennsaid)

Reference Number: CP.PMN.274
Effective Date: 03.01.22
Last Review Date: 02.22
Line of Business: Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Pennsaid® is a nonsteroidal anti-inflammatory drug (NSAID).

## FDA Approved Indication(s)

Pennsaid is indicated for the treatment of the pain of osteoarthritis (OA) of the knee(s).

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Pennsaid is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Osteoarthritis Pain** (must meet all)**:**

1. Diagnosis of OA;
2. Age ≥ 18 years;
3. Failure of ONE oral generic NSAID, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of generic diclofenac 1% topical gel, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 80 mg (4 pumps) per knee per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Osteoarthritis Pain** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 80 mg (4 pumps) per knee per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications**(must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid .

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
CABG: coronary artery bypass graft
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug
OA: osteoarthritis

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| ***Oral NSAIDs*** | | |
| diclofenac (Voltaren®) | 50 mg PO TID | 150 mg/day |
| etodolac (Lodine®) | 400 – 500 mg PO BID | 1,200 mg/day |
| fenoprofen (Nalfon®) | 400 – 600 mg PO TID to QID | 3,200 mg/day |
| ibuprofen (Motrin®) | 400 – 800 mg PO TID to QID | 3,200 mg/day |
| indomethacin (Indocin®) | 25 – 50 mg PO BID to TID | 200 mg/day |
| indomethacin SR (Indocin SR®) | 75 mg PO QD to BID | 150 mg/day |
| ketoprofen (Orudis®) | 50 mg PO QID or 75 mg PO TID | 300 mg/day |
| meloxicam (Mobic®) | 7.5 mg – 15 mg PO QD | 15 mg/day |
| naproxen (Naprosyn®) | 250 – 500 mg PO BID | 1,500 mg/day for up to 6 months |
| naproxen sodium (Anaprox®, Anaprox DS®) | 275 – 550 mg PO BID | 1,650 mg/day for up to 6 months |
| oxaprozin (Daypro®) | 600 – 1,200 mg PO QD | 1,800 mg/day |
| piroxicam (Feldene®) | 10 – 20 mg PO QD | 20 mg/day |
| salsalate (Disalcid®) | 500 – 750 mg PO TID, titrated up to 1,000 mg TID or 1500 mg BID | 3,000 mg/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| sulindac (Clinoril®) | 150 mg – 200 mg PO BID | 400 mg/day |
| tolmetin DS (Tolectin®) | 400 mg PO TID maintenance 200-600 mg TID | 1,800 mg/day |
| ***Topical NSAIDs*** | | |
| diclofenac 1% gel (Voltaren® Gel) | 2 – 4 g applied to affected area QID | 32 g/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the drug product;
  - History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients;
  - In the setting of coronary artery bypass graft (CABG) surgery
- Boxed warning(s):
  - Cardiovascular thrombotic events;
  - Gastrointestinal bleeding, ulceration, and perforation;
  - Use in the setting of CABG.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Pain of OA of the knee(s) | 40 mg (2 pump actuations) topically BID per knee | 80 mg/knee/day (4 pumps/knee/ day) |

## VI. Product Availability

Topical solution: 2%

## VII. References

1. Pennsaid Prescribing Information. Lake Forest, IL: Horizon Pharma USA Inc.; April 2021. Available at: www.pennsaid.com. Accessed August 19, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 7, 2021.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created per November SDC and prior clinical guidance. | 11.30.21 | 02.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.