Clinical Policy: Meloxicam (Vivlodex)

Reference Number: CP.CPA.296
Effective Date: 11.16.16
Last Review Date: 11.19
Line of Business: Commercial

Revision Log

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

Description

Meloxicam (Vivlodex™) is a non-steroidal anti-inflammatory drug (NSAID).

FDA Approved Indication

Vivlodex is indicated for the management of osteoarthritis (OA) pain.

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 Vivlodex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoarthritis or Rheumatoid Arthritis Pain (off-label) (must meet all):

1. Diagnosis of OA or rheumatoid arthritis;
2. Age ≥ 18 years;
3. Failure of generic meloxicam and one other preferred NSAID (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 10 mg per day.

Approval duration: Length of Benefit

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.CPA.09 for commercial.

II. Continued Therapy

A. Osteoarthritis or Rheumatoid Arthritis Pain (off-label) (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 10 mg per day.

Approval duration: Length of Benefit

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.CPA.09 for commercial.

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.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key:
CABG: coronary artery bypass graft
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
meloxicam (Mobic®)	7.5 mg -15 mg PO QD	15 mg/day
diclofenac sodium (Voltaren®)	50 mg PO TID	150 mg/day
etodolac (Lodine®)	400 - 500 mg PO BID	1200 mg/day
fenoprofen (Nalfon®)	200 mg PO Q4-6 hr	3200 mg/day
ibuprofen (Motrin®)	400 - 800 mg PO Q6-8 hr	3200 mg/day
indomethacin (Indocin®)	25 - 50 mg PO BID-TID	200 mg/day
indomethacin SR (Indocin® SR)	75 mg PO QD - BID	150 mg/day
ketoprofen (Orudis®)	25-75 mg PO Q6-8 hr	300 mg/day
meclofenamate (Meclomen®)	50 - 100 mg PO Q4-6 hr	400 mg/day
naproxen (Naprosyn®)	250 - 500 mg PO BID	1500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
naproxen sodium (Anaprox®, Anaprox DS®)	275 - 550 mg PO BID	1650 mg/day
oxaprozin	600 - 1,200 mg PO QD	1800 mg/day
piroxicam (Feldene®)	10 - 20 mg PO QD	20 mg/day
salsalate (Disalcid®)	500 - 750 mg PO BID-TID	3000 mg/day
sulindac (Clinoril®)	150 mg - 200 mg PO BID	400 mg/day
tolmetin (Tolectin®)	400 mg PO TID	1800 mg/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): hypersensitivity to meloxicam or any components of the drug product; history of asthma, urticarial, or other allergic-type reactions after taking aspirin or other NSAIDs; in the setting of coronary artery bypass graft (CABG) surgery
- Boxed warning(s): cardiovascular thrombotic events; gastrointestinal bleeding, ulceration, and perforation

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
OA or rheumatoid arthritis pain	5-10 mg PO QD	10 mg/day

VI. Product Availability

Capsules: 5 mg, 10 mg

VII. References

1. Vivlodex Prescribing Information. Philadelphia, PA: Iroko Pharmaceuticals, LLC; October 2015. Available at: www.vivlodex.com. Accessed on August 25, 2019.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thompson Healthcare. Updated periodically. Accessed August 25, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.22.17	11.17
4Q 2018 annual review: no significant changes; added age limit. References reviewed and updated.	07.16.18	11.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.25.19	11.19

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.