RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	meloxicam
Policy Number:	RxA.556
Drug(s) Applied:	Vivlodex®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Meloxicam (Vivlodex®) is a non-steroidal anti-inflammatory drug (NSAID). It is indicated for the management of osteoarthritis (OA) pain.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
meloxicam (Vivlodex®)	OA or rheumatoid arthritis pain	Initial, 5 mg PO once daily; may increase to 10 mg once daily if needed.	10 mg/day

Dosage Forms

- Capsules: 5 mg, 10 mg

Clinical Policy

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

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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance benefit or member has

previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CABG: coronary artery bypass graft
NSAID: non-steroidal anti-inflammatory drug
OA: osteoarthritis

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
meloxicam (Mobic®)	7.5 mg -15 mg PO once daily	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	75 mg PO QD - BID	150 mg/day
ketoprofen	25-75 mg PO Q6-8 hr	300 mg/day
meclofenamate	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 DS®)	275 - 550 mg PO BID	1500 mg/day
oxaprozin	600 - 1,200 mg PO once daily	1800 mg/day
piroxicam (Feldene®)	10 - 20 mg PO once daily	20 mg/day
salsalate (Disalcid®)	500 - 750 mg PO BID-TID	3000 mg/day
sulindac	150 mg - 200 mg PO BID	400 mg/day
tolmetin	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):
  - It causes an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal.
  - It is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
  - It causes an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

APPENDIX D: General Information

- Not Applicable

References

1. Vivlodex Prescribing Information. Philadelphia, PA: Iroko Pharmaceuticals, LLC; June 2020. Available at: www.vivlodex.com. Accessed on October 1, 2020.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thompson Healthcare. Updated periodically. Accessed October 1, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosing information was updated to include dose increasement to 10 mg daily if required. 5. APPENDIX B: "Therapeutic Alternatives verbiage was updated to Below are suggested therapeutic alternatives based on clinical guidance...." 6. APPENDIX B: was updated to remove some discontinued therapeutic alternatives brands like Indocin SR, Orudis, Meclomen, Anaprox, Clinoril, Tolectin. 7. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 8. Initial Approval criteria: Commercial and Medicaid approval duration were updated from length of benefit to 6 months. 9. Continued Approval criteria: Commercial and Medicaid approval duration were updated from length of benefit to 6 months. 10. APPENDIX C was updated to include details Boxed Warnings. 11. References were updated.	10/1/2020	12/07/2020