Pharmacy Policy Bulletin: J-0355 Vivlodex (meloxicam) - Commercial and Healthcare Reform	
Number: J-0355	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0355-013	**Original Date:** 12/02/2015
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Vivlodex (meloxicam)
FDA-Approved Indication(s):	• Management of osteoarthritis (OA) pain

Background:	• Vivlodex is a nonsteroidal anti-inflammatory (NSAID). Like other NSAIDs, the mechanism is not fully understood but involves the inhibition of cyclooxygenase (COX) I and II. This results in decreased inflammation, pain, and fever.
	• Vivlodex is a low dose formulation of meloxicam and is formulated in capsules containing submicron particles to provide increased surface area and faster dissolution rates.
	• Meloxicam was first introduced as Mobic tablets; generic meloxicam tablets are currently available.
	• Vivlodex was shown to be effective in clinical trials compared to placebo. It is unknown how it compares in efficacy and safety to standard-dose meloxicam.
	• Prescribing Considerations:
	  ○ NSAIDs, including Vivlodex, have a black box warning for increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, and gastrointestinal bleeding, ulceration, and perforation, which can be fatal.
	  ○ Vivlodex is contraindicated in the setting of known hypersensitivity, in patients with a history of asthma, urticaria, other allergic type reactions after taking aspirin or other NSAIDs, and in the setting of coronary artery bypass graft surgery.
	  ○ Additional warnings/precautions with Vivlodex are consistent with other NSAIDs, and include hepatotoxicity, hypertension, heart failure and edema, renal toxicity and hyperkalemia, serious skin reactions, anaphylactic reactions, drug reaction with eosinophilia and systemic

	symptoms, fetal toxicity, hematologic toxicity, and masking of inflammation and fever. ○ NSAIDs, including Vivlodex (meloxicam), can cause serious skin adverse reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. NSAIDs can also cause fixed drug eruption (FDE).

Approval Criteria

I. Initial Authorization
When a benefit, coverage of Vivlodex (meloxicam) may be approved when all of the following criteria are met **(A. B., and C.)**:
- **A.** The member has a diagnosis of osteoarthritis. (ICD-10: M15, M16, M17, M18, M19)
- **B.** The member has experienced therapeutic failure or intolerance to plan-preferred, generic meloxicam tablets.
- **C.** The member has experienced therapeutic failure, contraindication, or intolerance to two (2) additional plan-preferred, generic, formulary NSAIDs.

II. Reauthorization
When a benefit, reauthorization of Vivlodex (meloxicam) may be approved when the following criterion is met **(A.):**
- **A.** The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indication(s) should be denied based on the lack of clinical data to support effectiveness and safety in other conditions.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Vivlodex [package insert]. Princeton NJ: iCeutica Operations LLC; November 2024.
2. Iroko Pharmaceuticals receives FDA approval for VIVLODEX – first low dose SoluMatrix meloxicam for osteoarthritis pain. 2015. Available at: http://www.multivu.com/players/English/7268051-iroko-fda-approval/