



Provided as a Client Service by Healthcare Solutions' Clinical Pharmacy Team

FDA Approves New Analgesic Using Nanotechnology

Background:

Iroko Pharmaceuticals, LLC recently announced that the US Food and Drug Administration (FDA) received approval to begin marketing its new drug product Vivlodex™ (meloxicam).¹ Vivlodex™ is indicated for the management of osteoarthritis pain. Vivlodex™ will be available in strengths of 5 mg and 10 mg and should be taken once a day.² According to Iroko Pharmaceuticals, LLC Vivlodex™ is the first FDA-approved low dose SoluMatrix® meloxicam.¹ The pricing information and anticipated release date for this new product is unknown at time of publication.

Impact to Our Customers:

Nonsteroidal Anti-inflammatory Drugs (NSAIDs) were within the top 10 drugs by both spend and utilization for claims within Healthcare Solutions' book of business in 2014.³ Iroko Pharmaceuticals, LLC states that Vivlodex™ was developed to align with recommendations from FDA and many professional medical organizations that NSAIDs be used at the lowest effective dose for the shortest possible duration.^{1,4} Vivlodex™ is the third FDA-approved low dose NSAID developed by Iroko Pharmaceuticals, LLC.¹ The other two products are Zorvolex® (diclofenac) and Tivorbex® (indomethacin).⁵ Healthcare Solutions' Pharmacy and Therapeutics Committee (P&T) will evaluate whether to recommend coverage status of this medication in the future; at this time, however, the medication will require a prior authorization on our drug formularies.

For questions regarding this eAlert or to learn more about our Clinical Rx Services please contact your dedicated Account Executive.

Sources:

1. Iroko Pharmaceuticals, LLC. (2015). Iroko Pharmaceuticals Receives FDA Approval for Vivlodex™ — First Low Dose SoluMatrix® Meloxicam for Osteoarthritis Pain. [Press release]. Available at: <https://www.iroko.com/news/press-releases/>
2. Vivlodex™ [Package insert]. Philadelphia, Pennsylvania: Iroko Pharmaceuticals LLC. Available at: <https://www.vivlodex.com/wp-content/uploads/2015/10/vivlodex-prescribing-information.pdf>
3. Healthcare Solutions, Inc. (2015). 2015 Workers' Compensation Drug Trends Report. [Online]. Available at: http://issuu.com/healthcaresolutions0/docs/healthcare_solutions_2015_drug_tren
4. U.S. Food and Drug Administration (FDA). (2005). Public Health Advisory – FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). [Press release]. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm150314.htm>
5. Iroko Pharmaceuticals, LLC. (2015). Approved US Products. Available at: <https://www.iroko.com/products/approved-us-products/>

Healthcare Solutions' clinical pharmacist team actively monitors and communicates timely news and announcements from the FDA affecting prescription drug management. We are committed to notifying you of important information as well as offering consultation on how these updates may impact your claimants and pharmacy management program.

Disclaimer

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