Workers' Comp

Ask The Pharmacist: FDA Approval of Non-Opioid Medication for Acute Pain

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Does Journavx offer a safer alternative to opioids for acute pain relief in workers' compensation?

The U.S. Food and Drug Administration (FDA) recently approved Journavx (suzetrigine), a novel non-opioid medication developed by Vertex Pharmaceuticals for the treatment of moderate to severe acute pain in adults. This approval, announced on January 30, 2025, marks a significant milestone in pain management, introducing the first new class of oral medication for acute pain in over two decades.

Journavx, a selective Nav1.8 sodium channel inhibitor, offers a non-addictive alternative to opioids. Its unique mechanism of action targets pain signals without affecting the brain, thus avoiding the potential for addiction. This innovative approach could transform pain relief strategies, particularly in workers' compensation cases.

Key Features of Journavx

- Mechanism: Oral, non-addictive pain signal inhibitor
- Dosage: 100 mg loading dose, followed by 50 mg every 12 hours
- Duration: Use beyond 14 days hasn't been studied
- Current Average Wholesale Price (AWP): $18.60 per 50 mg tablet

Clinical Trial Results

Two large Phase 3 trials, NAVIGATE 1 and 2, evaluated Journavx in post-surgical pain after abdominoplasty and bunionectomy. The medication demonstrated:

- Statistically significant pain reduction compared to placebo
- Rapid onset of action, with median time to clinically meaningful pain relief of 119 minutes (abdominoplasty) and 240 minutes (bunionectomy)
- Effectiveness both as monotherapy and as part of multimodal pain management

Safety Profile

Journavx was generally safe and well-tolerated, with lower rates of adverse events compared to placebo and opioid comparators. Common side effects included itching, muscle spasms, rash, increased blood levels of creatine phosphokinase, nausea, constipation, headache and dizziness.

Implications for Workers' Compensation

The introduction of Journavx could have significant implications for workers' compensation programs, including:

- Non-opioid option for acute pain management
- Improved safety profile potentially leading to better tolerability
- Alignment with multimodal pain management approaches
- Potential impact on treatment costs and outcomes

Dr. Todd Bertoch, Chief Medical Officer for Pain Research at CenExel JBR Clinical Research, who led the Phase 3 clinical trials, suggests that Journavx is intended to be used as part of a step-up approach after acetaminophen and NSAIDs. It may also be considered for patients with contraindications to these medications.

Potential Limitations

While promising, it's important to note some limitations of the current data:

- Main trials focused on specific surgical models, which may not represent all types of acute pain in workers' compensation cases
- Short trial duration of 48 hours
- Failed to show superiority to hydrocodone/acetaminophen

The approval of Journavx represents a significant advancement in pain management, offering a non-opioid option for moderate to severe acute pain in adults. As more information becomes available, health care providers and workers' compensation programs will need to evaluate its place in pain management protocols and treatment guidelines.

This information is meant to serve as a general overview, and any specific questions should be fully reviewed with a health care professional such as the prescribing doctor or dispensing pharmacist.

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