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First Script Prescription Benefit News
for Workers' Compensation

January 2020

Drug of the Month

Reyvow® (lasmiditan)

In October 2019, the U.S. Food and Drug Administration (FDA) approved Reyvow, a new medication for the management of acute migraine symptoms, which is anticipated to be available in pharmacies in January 2020.[1]

Migraine medications are broadly used to prevent or treat migraine headache episodes. Preventative medications are taken continuously and are intended to reduce the frequency of migraines or prevent acute episodes of migraines. Acute treatment medications are intended to provide more immediate relief of symptoms once an episode has begun. A group of related medications categorized as triptans are most frequently prescribed for acute migraines and act partly by constricting blood vessels in the brain. Significant numbers of migraine sufferers either don't respond, don't tolerate, or have other contraindications to triptans. Given this, the markets arrival of additional treatment options for acute interruption of migraine symptoms is a welcome development.

Reyvow acts by engaging a unique serotonin receptor in the brain called 5HT-1F but differs from triptans in that it appears not to act by constricting blood vessels.[2] Older theories of causation for migraines hinged on the idea that they were related to over-dilation of blood vessels in the brain. More recently it has become understood that the causes of migraines extend beyond vasodilation to a number of other causes that aren't yet perfectly understood. In addition to Reyvow, another medication has been approved for migraine treatment called Ubrelvy®, which also acts through a mechanism that does not include vasoconstriction. Because Reyvow and Ubrelvy avoid vasoconstriction, neither carry a label warning against their use in patients with existing cardiovascular compromise that triptans do.

The most common side effects observed in clinical trials for Reyvow are dizziness, fatigue, paresthesia, and sedation. Reyvow is also a central nervous system (CNS) depressant and carries label warnings for driving impairment and additive risk in combination with alcohol or other CNS depressant substances.[3] The final approval and market availability of Reyvow is pending completion of a controlled substance evaluation by the Drug Enforcement Administration.

Because migraine headaches are not frequently considered compensable in workers' compensation, these new medications are not expected to rise to a significant level of utilization or related costs. Pricing information was not available at the time of this publication, but we expect that they will carry a cost of treatment that is significantly higher than the mature triptan products they seek to replace.

1. https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-patients-migraine
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6181111/
3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211280s000lbl.pdf

Governmental Activity by State

Find out more about the governmental updates and potential changes currently being proposed in your state

To find out more about the governmental updates and potential changes currently being proposed in your state, visit the Coventry News and Insights page each month to read our Government Relations Newsletter. Find this month's newsletter here.

Ask The Pharmacist

To suggest a topic, send an email to: AskThePharmacist@cvty.us.com

Is there a new concern related to Gabapentin use and serious breathing problems?

In a new drug safety communication from FDA Medwatch the FDA warns about serious breathing difficulties related to the use of gabapentinoid (GabaP) medications in patients with other respiratory risk factors.[1] Elderly patients and others with existing respiratory ailments, such as COPD or asthma, and/or those that are co-prescribed GabaPs and central nervous system (CNS) depressants (e.g. opioids, benzodiazepines, muscle relaxants, or sedative-hypnotics) are cautioned regarding an increased risk for respiratory compromise and distress.[1] The FDA is requiring that new warnings be added to the prescribing information for these medications and that additional studies be conducted to further evaluate their additive risk for respiratory depression and abuse potential in combination with opioid medications.

Gabapentinoids, such as Lyrica®, Neurontin®, Gralise®, Horizant®, gabapentin, and pregabalin, are frequently prescribed in the workers' compensation setting, alone and in combination with other analgesics, for neuropathic and mixed pain conditions. They have recently seen significant growth in prescription volumes, due in part to an unsatisfied need for safer, effective alternatives to opioid medications. GabaPs carry FDA-approved indications for the management of partial seizures, as well as for nerve pain from spinal cord injury, diabetic neuropathies, or post-herpetic neuralgia (shingles).[2] Fibromyalgia and restless leg syndrome are also approved uses.

Common side effects of GabaPs include sleepiness, dizziness, fatigue, and tremor. More serious side effects include suicidality, angioedema, and shallow breathing.[2] This new warning from the FDA is prompted by a number of case reports and the results of several clinical trials that indicate new awareness of serious breathing difficulties, especially when concomitant use of GabaPs and opioids or other CNS depressants is evident.

Although the euphoriant potential of GabaPs alone is thought to be minimal, they are reportedly misused on the "street premise" that they increase the effects of other substances of abuse. Misuse of GabaP in combination with other substances that inhibit respiration may carry similar risks for respiratory compromise and life-threatening emergencies.

Injured workers and caregivers should be alert to symptoms of distress and seek immediate medical attention if symptoms are observed, as these can be very serious, even life-threatening. These may include:

- Confusion or disorientation
- Unusual dizziness or light-headedness
- Extreme sleepiness or lethargy
- Slowed, shallow, or difficult breathing
- Unresponsiveness (subject doesn't respond or react normally, can't be awakened)
- Bluish-colored or tinted skin, especially on lips, fingers, and toes

Prescribers considering treatment with GabaPs should take note of existing respiratory conditions, co-prescribed CNS depressants, or other potential exposures and consider dose adjustments or treatment alternatives that mitigate this potential risk. GabaP treatment should begin at the lowest effective dose and be carefully monitored, especially for injured workers with existing respiratory risks. Tricyclic antidepressants, serotonin selective reuptake inhibitors (SSRI), serotonin-norepinephrine reuptake inhibitor (SNRI) medications, duloxetine, nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen may all offer possibilities for added pain relief without added CNS-depressant properties.

Please contact your First Script account manager or clinical pharmacist with any questions or concerns you may have regarding this new warning.

1. FDA Drug Safety Communication – 12/19/2019 – Accessed at https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin
2. Lyrica Prescribing Information – Accessed at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021446s026,022488s005lbl.pdf

Clinical Update

UBRELVY™ Approval on December 23, 2019

The FDA has recently approved UBRELVY for the treatment of migraine attacks in adults. To find out more about UBRELVY, read our First Script bulletin.