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DEA moves Tramadol to Schedule IV

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The Drug Enforcement Agency (DEA) announced on July 2, 2014 the decision to place Tramadol on the Schedule IV drug controlled substance list effective August 18, 2014. Tramadol is a central acting opioid analgesic for the treatment of moderate to moderately severe pain in adults. It was first approved by the Food and Drug Administration (FDA) in 1995.

When Tramadol was initially approved by the FDA, the potential for abuse and dependence was unknown. In recent years studies have shown there is some risk.

Unlike Norco and Vicodin (both Schedule III drugs being moved to the Schedule II list), Tramadol is significantly less potent and is much less likely to be abused. Placing Tramadol on the Schedule IV list places it in the same "safety" category as benzodiazepines, Soma (carisoprodol) and Ambien. However, the side effects of benzodiazepines, Soma and Ambien, are far more severe than those of Tramadol and dependence is a much greater risk.

The most severe side effect of Tramadol is Serotonin Syndrome. According to MedLine Plus some symptoms of Serotonin Syndrome include agitation, ataxia, hallucinations, fast heartbeat, high blood pressure, increased body temperature, diarrhea, fever, hyperreflexia and shivering. Serotonin Syndrome is usually only experienced in patients taking two or more drugs that affect serotonin levels in the body. According to WebMD, many drugs that can cause Serotonin Syndrome are anti-depressants, mirtazapine, selective serotonin reuptake inhibitors, tricyclics, venlafaxine, bupropion, carbamazepine, lithium, morphine, pethidine, reserpine, sibutramine and St. John's Wort. Therefore, it is important for a utilization review physician to review all of the medications a patient is taking to ensure the medical necessity of the prescribed drugs.

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No Refills Needed After Weaning, Tapering and Cessation

Drug Update

- Tramadol
- Norco
- Vicodin

- Back Page Update - Targiniq ER

Targiniq ER

On July 23, 2014, the FDA approved Targiniq ER, an extend release formulation of Oxycodone and Naloxone. According to the FDA press release, it is intended to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which immediate release medications are inadequate.

Targiniq ER was engineered with an abuse deterrent formulation. If the tablet is crushed and snorted or crushed, dissolved and snorted, the Naloxone negates the euphoric effects of the Oxycodone. However, Purdue Pharma L.P., the manufacturer of Targiniq ER, states that there is no way to prevent abuse by taking the tablet orally. The FDA press release states, "Targiniq ER can still be abused, including when taken orally (by mouth), which is currently the most common way Oxycodone is abused. It is important to note that taking too much Targiniq ER for purposes of abuse or by accident, can cause an overdose that can result in death."

Proponents of Targiniq ER, including Sharon Hertz, M.D., deputy director of the Division of Anesthesia, Analgesia and Addiction Products in the FDA's Center for Drug Evaluation and Research, say it is part of the effort to create more abuse deterrent medications to curb the opioid epidemic.

Opponents of Targiniq ER in the workers' compensation industry argue that few injured workers snort or inject their medications, rather they take the medications orally. In the workers' compensation arena, this is simply a more expensive brand name drug than the existing generic OxyContin on the market today.

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Contact Us

Give us a call for more information about our pharmacy review program for management of drugs including tapering, weaning and cessation

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