CENTRAL NERVOUS SYSTEM STIMULANTS: INCREASING THE RISK AND COST OF PAIN MANAGEMENT

There has been significant focus over the last few years on the use of opioids for chronic noncancerous pain management. But often overlooked are the associated risks and costs of treating the side effects of opioids, especially opioid-induced sedation (OIS). The reported incidence of opioid-induced sedation is between 20 and 60 percent of all patients taking opioids.[1] It commonly occurs during the initial phases of opioid therapy or with dose increases.[2] In the past, OIS was managed by making dosing adjustments in the narcotics or changing to a different opioid. Today, we are seeing physicians prescribe stimulants "off-label" to counteract the sedating effects of narcotics. Off-label means the medication is being used in a manner not specifically approved by the FDA. Off- label prescribing is entirely legal and common, but it can expose patients to risky and ineffective treatments. Despite being used to counteract the sedating effects of prescription opioids, benzodiazepines, and hypnotics, these central nervous system stimulants carry their own risks such as dependence, abuse, fatal skin reactions, decreasing the effectiveness of other medications, depression, and hallucinations.

Two of the newer stimulants (aka wakefulness-promoting agents) on the market today are Provigil® (modafinil) and Nuvigil® (armodafinil). These medications are FDA-approved for narcolepsy, obstructive sleep apnea, and shift-work disorder. Other stimulants prescribed to treat attention-deficit hyperactivity disorders such as Ritalin® (methylphenidate) and Concerta® have also been prescribed for OIS. None of these stimulants have FDA indication for OIS. There is very little research to support their efficacy, and there is almost no data demonstrating safety. Only methylphenidate has been studied for the treatment of opioid-induced sedation, but its use is still not widely supported.[3] According to the *Official Disability Guidelines (ODG)*, the stimulant modafinil (Provigil®) is "not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing." These drugs have been known to be misused and/or abused, particularly by patients who have a history of drug dependence or alcoholism. Adding medications to treat adverse effects from other medications may create hazardous drug-to-drug interactions and higher costs.

The Minnesota Treatment Parameters do not specifically cite guidelines for the use of stimulants or off-label medication, but Rule 5221.6050 General Treatment Parameters Subpart 1(B) does provide some general guidance to consider.

No later than any applicable treatment response time in parts 5221.6200 to 5221.6305, the health care provider must evaluate whether the passive, active, injection, or medication treatment modality is resulting in progressive improvement as specified in subitems (1) to (3):

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[1] Cherny N, Ripamonti C, Pereira J, Davis C, Fallon M, McQuay H, et al. Strategies to manage the adverse effects of oral morphine: an evidence-based report. *J Clin Oncol*. 2001;19:2542–54.

[2] McNicol E, Horowicz-Mehler N, Fisk RA, Bennett K, Gialeli-Goudas M, Chew PW, et al. Management of opioid side effects in cancer- related and chronic noncancer pain: a systematic review. *J Pain*. 2003;4:231–56.

[3] Reissig JE & Rybarczyk AM. Pharmacologic Treatment of Opioid-Induced Sedation in Chronic Pain. *The Annals of Pharmacotherapy*. 2005; (39): 727-731.

(1)the employee's subjective complaints of pain or disability are progressively improving, as evidenced by documentation in the medical record of decreased distribution, frequency, or intensity of symptoms;

(2) the objective clinical findings are progressively improving, as evidenced by documentation in the medical record of resolution or objectively measured improvement in physical signs of injury; and

(3) the employee's functional status, especially vocational activities, is progressively improving, as evidenced by documentation in the medical record, or successive reports of work ability, of less restrictive limitations on activity.

In addition to risk and safety concerns, these medications can be very expensive. Provigil is consistently one of the top 25 medications prescribed in workers' compensation claims and comes with a price tag of about $40 per tablet for brand or $20 per tablet for generic. The standard dose of Provigil® is 200 mg given once a day, which may result in a monthly cost of $1,200.

With prescription drugs now accounting for about 19 percent of workers' compensation medical costs[4], effective prescription management approaches are vital to managing cost. But beyond that, effective prescription management approaches must also focus on the patient's health and safety. Providers also need to be educated to ensure they are following best practices, and patients need to be clearly informed of the risks involved, especially when taking multiple medications.

FOR MORE INFORMATION ON CNS STIMULANTS

Read "Central Nervous System Stimulant Use on the Rise" in the Spring 2013 issue of the Healthesystems *RxInformer* clinical journal.

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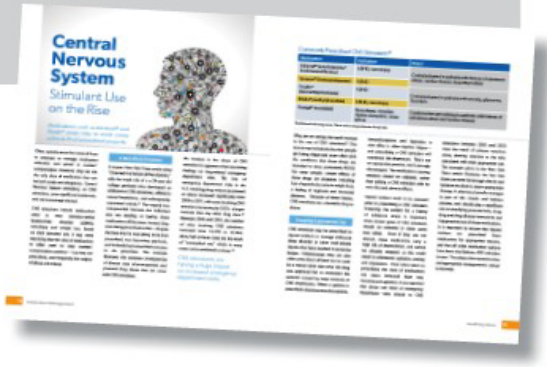

[4] NCCI Research Brief – https://www.ncci.com/documents/2011_ncci_research_rxdrug_study.pd

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