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DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review in Iowa

Gabapentinoid Abuse

In February 2018, the then Food and Drug Administration (FDA) Commissioner, Scott Gottlieb, MD, made remarks at the Public Workshop on Strategies for Promoting the Safe Use and Appropriate Prescribing of Prescription Opioids regarding the opioid addiction epidemic. He spoke to how in the early days of the opioid epidemic, many people characterized opioid addiction as a problem of non-medical abuse. Evidence suggested otherwise, as addiction was occurring in both medical and non-medical users, rather than abuse alone and was a key driver of the epidemic. As a nation, we were slow to recognize this.

Gabapentin is FDA approved for the treatment of partial onset seizures, with and without secondary generalization, and in the management of postherpetic neuralgia in adults. Pregabalin is FDA approved for the management of neuropathic pain associated with diabetic peripheral neuropathy or spinal cord injury, postherpetic neuralgia, partial onset seizures, and fibromyalgia. "Some literature suggests that clinicians may be prescribing these drugs off-label…as alternative to opioids, outside approved indications," Gottlieb said.

"Our preliminary findings show that abuse of gabapentinoids doesn't yet appear to be widespread, but use continues to increase, especially for gabapentin," he said. "FDA is investigating whether abuse or misuse is also increasing and if so, what should be done to address this problem." Although the data are limited, they do suggest that gabapentinoid abuse and misuse "may be growing, both when taken alone and in combination with opioids, benzodiazepines, or other central nervous system depressants," Gottlieb continued.

The FDA has taken steps to analyze the potential for misuse and abuse of gabapentinoids. They have looked at social media sites where opioid users share comments that describe methods and motivations for misusing or abusing gabapentinoids. They've also tasked their surveillance and epidemiology group, who are focused on spotting early patterns of abuse of controlled substances.

Through the review of the Fee-for-Service (FFS) and Managed Care Organization (MCO) prevalence reports, it has been noted gabapentin utilization has been increasing. Due to the reports of potential abuse, ProDUR quantity limits on gabapentin will be implemented (quantity limits are currently in place for pregabalin). Quantity limits for gabapentin immediate release (IR) are as follows:

Strength	Daily Quantity Limit	Monthly Quantity Limit
100 mg	6 capsules	180 capsules
300 mg	9 capsules	270 capsules
400 mg	9 capsules/tablets	270 capsules/tablets
600 mg	6 tablets	180 capsules
800 mg	4.5 tablets	135 tablets
50 mg/mL	72 mL	2160 mL

In addition to the above daily limits for the number of units per day, a daily milligram (mg) per day dose limit will be implemented, accumulating mg across all strengths in a members claims. Maximum dose for gabapentin IR is 3600 mg; pregabalin IR is 600 mg.

FDA Drug Safety Communications

April 30, 2019 The Food and Drug Administration (FDA) is advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with eszopiclone, zaleplon, and zolpidem than other prescription medicines used for sleep. As a result, the FDA is requiring a *Boxed Warning* to be added to the prescribing information and the patient Medication Guides. In addition, a *Contraindication is being added*, to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem.

April 9, 2019 The FDA has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. While the FDA continues to track this safety concern as part of their ongoing monitoring of risks associated with opioid pain medicines, they are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

High Dose Opioids – MME Decrease

Effective October 1, 2019, PA is required for use of high dose opioids ≥ 120 morphine milligram equivalents (MME) per day. Patients undergoing active cancer treatment or end-of-life care will not be subject to PA criteria. The MME edit will gradually be decreased over time to 90 MME per day. PA requests should be submitted on the most current High Dose Opioids PA form found at: http://www.iowamedicaidpdl.com under the PA Forms link on the left hand side of the page.

Medicaid Statistics for Prescription Claims
June 2019 through August 2019

	FFS	Amerigroup	Iowa Total Care*	United Healthcare^
# Paid Claims	32,000	1,026,980	498,371	374,341
Total $ Paid	$2,743,177	$93,693,230	$38,628,855	$28,090,039
Unique Users	7,000	149,829	91,173	109,234
Avg Cost/Rx	$85.72	$91.23	$77.51	$75.04
Top 5 Drugs by Prescription Count	Hydrocodone/APAP	Omeprazole	Omeprazole	Lisinopril
	Trazodone	Lisinopril	Lisinopril	Levothyroxine
	Omeprazole	Atorvastatin	Atorvastatin	Atorvastatin
	Lisinopril	Levothyroxine	Sertraline	Sertraline
	Proair HFA	Sertraline	Levothyroxine	Omeprazole
Top 5 Drugs by Paid Amount (pre-rebate)	Acthar	Vyvanse	Humira Pen	Humira Pen
	Humira Pen	Concerta	Vyvanse	Vyvanse
	Vyvanse	Latuda	Latuda	Concerta
	Concerta	Humira (CF) Pen	Invega Sustenna	Latuda
	Proair HFA	Humalog	Humalog	Humalog
Top 5 Therapeutic Class by Paid Amount (pre-rebate) Therapeutic class taxonomy differs among each plan	Glucocorticoids – Corticotropin	Antidiabetics	Insulin	Insulins
	Anti-Inflammatories, Non-NSAID	ADHD/Anti-Narcolepsy	Sympathomimetics	Anti-Inflammatory TNF Inhibitor
	Anticonvulsants	Antipsycotics/ Antimanic Agents	Anti-TNF-Alpha - Monoclonal Antibodies	Antipsychotic,Atypical,Dopamine, Serotonin Antagnst
	Antiretroviral Combinations	Antiasthmatic & Bronchodilator Agents	Antiretrovirals	Tx for ADHD/Narcolepsy
	Antipsychotics - Atypicals	Analgesics – Anti-Inflammatory	Amphetamines	Anticonvulsants
Top 5 Therapeutic Class by Prescription Count Therapeutic class taxonomy differs among each plan	Antidepressants – Selected SSRI's	Antidepressants	SSRIs	SSRIs
	Anticonvulsants	Anticonvulsants	Anticonvulsants - Misc.	Anticonvulsants
	Antipsychotics – Atypicals	Antiasthmatic & Bronchodilator Agents	Sympathomimetics	PPIs
	Antihypertensives – Central	Antihypertensives	PPIs	Antihyperlipidemic HMG CoA Reductase Inhib.
	Narcotics – Misc.	Ulcer Drugs/antispasmodics Anticholinergics	HMG CoA Reductase Inhibitors	Antihistamines – 2nd Generation

* Claims for July and August only

^ Claims for June only