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New Medications to be Added to the Connecticut Prescription Monitoring and Reporting System (CPMRS)

Introduction

The Connecticut Department of Consumer Protection (the Department) is now requiring Gabapentin and Naloxone dispensation information to be uploaded into the CPMRS effective January 1, 2021. The Department believes that the addition of this information will be valuable to practitioners, pharmacists and others in making appropriate decisions about the medical treatment of patients in Connecticut.

Authority

Currently, all dispensing of controlled substances in schedules II-V must be reported, pursuant to Section 21a-254(j) of the Connecticut General Statutes, into the CPMRS. Under Section 21a-254(j)(2) the Commissioner of Consumer Protection has the authority to add any products or substances to the CPMRS.

Adding Gabapentin to the CPMRS will provide an additional data point to assist prescribers and pharmacists in the decision to prescribe or dispense a medication. At this time, the addition does not change Gabapentin to a controlled substance and therefore it would not be subjected to mandatory look-up prior to prescribing.

Naloxone availability has also been on the rise, and due to its lifesaving use, reporting aggregate level data regarding the access to naloxone in Connecticut would help healthcare practitioners and policy makers as they continue to address the challenges surrounding accidental overdoses.

Gabapentin

Gabapentin is used to control seizures in certain types of epilepsy and treat certain types of nerve pain. It is commonly prescribed to relieve nerve pain following shingles in adults, treating the pain of post herpetic neuralgia. Gabapentin belongs to a class of drugs known as anti-seizure drugs. It is a GABA analogue (similar structurally) and is currently not a scheduled medication.

This product is available in the following dosage forms:

- Capsules;
- Tablets;
- Solutions; and
- Suspension.

Gabapentin is sold under the following brand names (not all inclusive):

- Active-PAC with Gabapentin: Oral capsule;
- Gralise: Oral tablet, extended release;
- Horizant: Oral tablet, extended release; and
- Neurontin: Oral capsule, tablet, solution.

Strengths Available (not all inclusive)

Oral capsule 100mg, 300 mg, 400 mg;
Oral tablets 600 mg, 800 mg; and
Oral solution 250 mg per 5 mL (50 mg per mL).

Based on the package insert from Neurontin ® (gabapentin) the therapeutic dosing range is from 100 mg daily to up to 3,600 mg. (https://www.pfizermedicalinformation.com/en-us/neurontin/dosage-admin) and states the following : Gabapentin does not exhibit affinity for benzodiazepine, opiate (mu, delta or kappa), or cannabinoid 1 receptor sites.

Abuse

A small number of post marketing cases report Gabapentin misuse and abuse. These individuals were taking higher than recommended doses of Gabapentin for unapproved uses. Most of the individuals described in these reports had a history of poly-substance abuse or used Gabapentin to relieve symptoms of withdrawal from other substances. When prescribing Gabapentin carefully evaluate patients for a history of drug abuse and observe them for signs and symptoms of Gabapentin misuse or abuse (e.g., development of tolerance, self-dose escalation, and drug-seeking behavior). https://www.pfizermedicalinformation.com/en-us/neurontin/drug-abuse

Other States

According to the Prescription Drug Monitoring Program Training and Technical Assistance Center, many other states have, or are in the process of adding Gabapentin into their Prescription Drug Monitoring Program (PDMP). The District of Columbia, Indiana, Kansas,

Massachusetts, Minnesota, New Jersey, Ohio, West Virginia, Wyoming have all incorporated the Gabapentin into their PDMP. In 2018 Minnesota stated Gabapentin as the number one prescription reported to their PDMP.
http://pmp.pharmacy.state.mn.us/assets/files/2018%20Files/Quarterly%20Reports/2018Q4_ReportII.pdf

Publications

In recent years, prescriptions for Gabapentin have been on the rise and found to possibly play a role in overdose deaths along with prescribed opioids. According to the Journal of Forensic Sciences, most of the deaths in which Gabapentin played a role (either causative or contributory) were also positive for at least one opioid. The most commonly present opiates in combination with lethal Gabapentin were oxycodone, hydrocodone, and buprenorphine. Clinicians who prescribe Gabapentin as an opiate alternative in the chronic pain population, specifically those with a history of abuse, should follow these patients closely to determine if there is diversion or misuse. This can be done via pill counts, drug testing, and now also use the CPMRS as a tool to view patient controlled substance medication history.

According to the article Multi Briefs: by Jason Poquette, states are responding to the rising prescribed drug, Gabapentin, by requiring the dispensing data to be uploaded to the states' prescription monitoring systems. For example, the State of Ohio Board of Pharmacy.

Office of the Connecticut Medical Examiner (OCME)

In June 2019, Gabapentin became a standard part of the toxicology screening panel utilized by the OCME in potential accidental overdose deaths. From July 2019 to December 2019, there were a total of 656 deaths that the OCME identified as accidental. Of those accidental overdose deaths, the toxicology report identified eighty (80) individuals with Gabapentin in their system (12%). If you were to extrapolate that data to the entire 2019 calendar year, Gabapentin was involved in approximately 144 accidental overdoses which is more than the following other substances:

- Fentanyl + Prescription Opioid
- Heroin + Cocaine
- Methadone
- Oxycodone
- Hydrocodone
- Hydromorphone
- Buprenorphine
- Xylazine
- Amphetamine/Methamphetamine

It is important to note that with the Gabapentin data obtained from the OCME, the medication was always present with at least one other substances. The role of Gabapentin in the

accidental overdose is difficult to ascertain due to the variety of substances involved. Generally, Gabapentin can be a safe and effective medication when used under the care of the prescribing practitioner and when the instructions from medical professional are followed by the patient.

The number of individuals who have Gabapentin present in an accidental overdose is significant enough to add Gabapentin dispensation into the CPRMS.

Note: The Department is not changing the controlled substance scheduling of Gabapentin at this time. As such, the CPMRS look-up requirements do not apply to Gabapentin prescribing.

Naloxone

Naloxone, also known as Narcan, is an "opioid antagonist" used to counter the effects of opioid overdose. Naloxone is a life-saving medication. This drug may be administered intravenously, intramuscularly, or subcutaneous, however, the injection is the most rapid onset of action that is achieved and is recommended in emergency situations.

Naloxone is injected into a muscle, under the skin, or into a vein through an IV. This injection may be given by a healthcare provider, emergency medical provider, or a family member or caregiver who is trained to properly give a naloxone injection. It is important to note that naloxone is non-addicting prescription medicine.

Naloxone (Narcan) can also be administered in a nasal spray, which require specialized training to use, however, you must get emergency medical help right away after giving the first dose.

The use of Naloxone for Opioid overdoses:

Intravenously: Initial dose 0.4mg to 2mg IV; alternatively, may give IM or subcutaneously;
Auto-Injector: For emergency use in the home or other non-medical setting. Administer 0.4mg (1 actuation) IM or subcutaneously into the anterolateral aspect of the thigh (through clothing if necessary);
Nasal Spray: Administer 1 spray intranasally into 1 nostril, dosages differ from adolescent use.
Naloxone is used to counteract drugs such as Morphine, Heroin, Codeine, Fentanyl, Hydrocodone, Methadone, and Oxycodone. It is important to note that there are risks to using Naloxone such as precipitation of severe opioid withdrawal, risk of cardiovascular effects and adverse reactions like muscle spasms. Naloxone only works if a person has opioids in their system; the medication has no effect if opioids are absent.

Currently, nineteen states and the North Mariana Islands collect naloxone dispensations in their prescription monitoring program including Arizona, Idaho, Illinois, Iowa, Maine, Maryland,

Massachusetts, Michigan, Nebraska, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Virginia, West Virginia, Wisconsin and Wyoming.

The naloxone information that is uploaded into the CPMRS will be masked from all users of the CPMRS except for administrators at the Department. The purpose of this data upload is to allow the program to report out the prescribing activity of naloxone in aggregate while preventing the inappropriate use of this information. Reviewing this data in aggregate will help to inform public policy regarding naloxone in the future.

Conclusion

The Deparment is adding Gabapentin and Naloxone because these are drugs that should be closely monitored and examined for the benefit of prescribers, pharmacists and others in Connecticut. This data will assist The Department and others in finding ways to help prevent future overdoses and conduct risk assessments for the patients in our state. Above is enough evidence for the Department to confidently pursue the implementation of both Gabapentin and Naloxone in Connecticut's database as other states have done.

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Naloxone:
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