Script Notes

AmeriHealth Caritas Northeast | AmeriHealth Caritas Pennsylvania

The Pharmacy and Therapeutics Newsletter for AmeriHealth Caritas Participating Providers

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In this issue

Centers for Disease Control and Prevention (CDC) Opioid Prescribing Guidelines: A Step in the Right Direction

History of opioid prescribing in the United States

Opioids, such as morphine, have been widely used for the treatment of pain since the Civil War era. After the discovery of the addictive properties of morphine, scientists and pharmaceutical companies attempted to design effective, but less addictive, pain medications. Despite the development of various pain medications in the 20th century, during the 1970s and 1980s, physicians were hesitant to prescribe these medications due to fear of addiction. Their prescribing habits changed, however, in the 1990s, with the development of long-acting opioid products. Numerous studies by pharmaceutical companies and statements from physicians claimed these medications had a low potential for abuse and adverse effects. These statements, compounded by an increased focus on treating pain, led to a surge in opioid prescribing.[1]

Positives and negatives

When prescribed at appropriate doses and in combination with other therapies, opioids can be effective for both acute and chronic nociceptive pain.[2] However, they can also cause numerous side effects including constipation, nausea and vomiting, sleepiness and dizziness, confusion, depression, and respiratory depression. Patients taking opioids can also develop tolerance and physical dependence. This means patients have to take more of the medication to achieve the same level of pain relief and may have withdrawal symptoms if the medication is stopped suddenly. In patients with certain risk factors (Table 1), physical dependence can develop into abuse, addiction, and overdose.[3]

Table 1: Risk factors for opioid abuse and overdose[3]

Filling prescriptions from multiple providers at multiple pharmacies
Taking high daily doses of opioid medications
Having a history of mental illness or substance abuse
Living in a rural area with a low income

Key points

- During 1999 to 2014, opioid prescribing, abuse, overdose, and related death have increased significantly.[4-6]
- To decrease the amount of opioid abuse and related death, the Centers for Disease Control and Prevention (CDC) created an evidence-based guideline for the prescribing of opioids.
- Some important points from the guideline include:
  - Nonpharmacologic and nonopioid therapies should be tried first.
  - If opioids are added, they should be an immediate release product, prescribed at the lowest effective dose for the shortest period of time.
  - Providers should monitor for abuse risk factors and treat any use disorder that may arise.[7]

Problem and potential solution

According to the CDC, "sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014."[4] Due to the addictive properties of opioids, with the increase in prescribing came an increase in opioid abuse, overdose, and death. In 2014, "almost 2 million Americans abused or were dependent on prescription opioids," and over 28,000 people died from an opioid-related overdose.[5,6] Despite this increase in opioid use, patients are still experiencing pain.

Government agencies have developed a multifactorial approach to combat the opioid epidemic and poor pain control in this country. One of the main components of their strategy is to improve the prescribing of opioids through the use of evidence-based guidelines.[6]

CDC opioid prescribing guidelines

In March 2016, the CDC released the "Guideline for Prescribing Opioids for Chronic Pain." The guideline was created by a group of pain management experts based on the best available evidence. It contains three sets of recommendations (Table 2) for primary care providers treating pain in adults, excluding "active cancer treatment, palliative care, and end-of-life care."[7] The first set of recommendations focuses on establishing realistic goals of therapy and when to initiate opioid therapy. According to the guideline, nonpharmacologic and nonopioid therapies (Table 3) should be tried first. Opioids can then be added, provided the benefits outweigh the risks and the patient fully understands and consents to those risks. The second set of recommendations stress that when an opioid is added, it should be an immediate release product, prescribed at the lowest effective dose for the shortest period of time. These recommendations are based on studies that show less benefit and greater risk when opioids are used alone, at high doses, and for an extended period. The last set emphasizes evaluating patients' risk factors

for addiction before initiating therapy, using prescription drug monitoring programs, and monitoring the patient throughout therapy. Should a patient develop an opioid use disorder, the guideline states that evidence-based treatment regimens with medications such as buprenorphine or methadone should be used.[7] Along with the guideline, the CDC created educational materials to help patients and physicians understand opioids, pain treatment, and the steps being taken to combat the problems the country currently faces.[10]

Although critics of the guideline exist, it is a step in the right direction. The positive impact of opioid prescribing guidelines, in general, has already been seen in the state of Washington where a guideline was implemented in 2007. The state has since seen a decrease in opioid-related deaths and hospitalizations through 2014, the last year of study follow-up.[11] Through the CDC guideline, pain is addressed holistically and based on the best available evidence. Steps will also be taken to minimize patients' risk of addiction and opioid-related side effects.

Lastly, the call for greater monitoring during therapy will help limit abuse and addiction and allow affected patients to receive appropriate care. To better conquer this epidemic, patients, health care providers, and the government need to continue to align their goals and take greater strides to improve pain management and fight abuse, addiction, and overdose.

Table 2: CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care[7]

Determining when to initiate or continue opioids for chronic pain
Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
Before and during opioid therapy, clinicians should discuss known risks and realistic benefits of opioid therapy with patients, and patient and clinician responsibilities for managing therapy.
Opioid selection, dosage, duration, follow-up, and discontinuation
When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day.
Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy or escalating dosage for chronic pain. Clinicians should evaluate benefits and harms of continued therapy with patients at least every three months. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.
Assessing risk and addressing harms of opioid use
Before and during opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/d), or concurrent benzodiazepine use are present.
Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.
When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

Table 3: Nonpharmacologic and nonopioid alternatives for pain treatment[7-9]

Nonpharmacologic	Nonopioid
Physical/exercise therapy	Acetaminophen
Weight loss	Non-steroidal anti-inflammatory drugs (NSAIDs) (oral or topical)
Psychological therapy	Anticonvulsants: • Gabapentin • Lyrica
Interventional treatments:[9] • Epidural injections • Nerve blocks • Spinal cord stimulation • Infusion systems	Antidepressants • Serotonin and norepinephrine reuptake inhibitors (SNRIs) • Tricyclic antidepressants (TCAs)

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FDA Medwatch Update

Fluoroquinolone Antibacterial Drugs for Systemic Use: Drug Safety Communication — Warnings Updated Due to Disabling Side Effects

Issue: The U.S. Food and Drug Administration (FDA) approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or injection). These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient. As a result, FDA revised the Boxed Warning, FDA's strongest warning, to address these serious safety issues. In addition, FDA updated other parts of the drug label, including the Warnings and Precautions and Medication Guide sections.

FDA has determined that fluoroquinolones should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis (ABS), acute exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risk of these serious side effects generally outweighs the benefits in these patients. For some serious bacterial infections, the benefits of fluoroquinolones outweigh the risks, and it is appropriate for them to remain available as a therapeutic option.

FDA is continuing to assess safety issues with fluoroquinolones as part of FDA's usual ongoing review of drugs and will update the public if additional actions are needed. See the FDA Drug Safety Communication for additional information, including the Data Summary and Additional Information for Health Care Professionals and Patients.

Recommendation: Patients must contact their health care professional immediately if they experience any serious side effects while taking their fluoroquinolone medicine. Some signs and symptoms of serious side effects include unusual joint or tendon pain, muscle weakness, a "pins and needles" tingling or pricking sensation, numbness in the arms or legs, confusion, and hallucinations. Patients should talk with their health care professional if they have any questions or concerns.

Health care professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for ABS, ABECB, and uncomplicated UTI, because the risks outweigh the benefits in these patients. If a patient reports serious side effects, stop fluoroquinolone treatment immediately and switch to a non-fluoroquinolone antibacterial drug to complete the patient's treatment course.

Canagliflozin (Invokana and Invokamet) and Dapagliflozin (Farxiga and Xigduo XR): Drug Safety Communication — Strengthened Kidney Warnings

Issue: FDA has strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin (Invokana and Invokamet) and dapagliflozin

(Farxiga and Xigduo XR). Based on recent reports, we have revised the warnings in the drug labels to include information about acute kidney injury and added recommendations to minimize this risk.

Recommendation: Health care professionals should consider factors that may predispose patients to acute kidney injury prior to starting them on canagliflozin or dapagliflozin. These include decreased blood volume, chronic kidney insufficiency, congestive heart failure, and taking other medications such as diuretics, blood pressure medicines called angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), and nonsteroidal anti-inflammatory drugs (NSAIDs). Assess kidney function prior to starting canagliflozin or dapagliflozin and monitor periodically thereafter. If acute kidney injury occurs, promptly discontinue the drug and treat the kidney impairment.

Patients should seek medical attention immediately if they experience signs and symptoms of acute kidney injury. This is a serious condition in which the kidneys suddenly stop working, causing dangerous levels of waste to build up in the body. Signs and symptoms of acute kidney injury may include decreased urine or swelling in the legs or feet. Patients should not stop taking their medicine without first talking to their health care professional. Doing so can lead to uncontrolled blood sugar levels that can be harmful. Read the patient Medication Guide you receive with your canagliflozin or dapagliflozin prescriptions. It explains the benefits and risks associated with the medicine.

Zecuity (Sumatriptan) Migraine Patch: Drug Safety Communication — FDA Evaluating Risk of Burns and Scars

Issue: FDA is investigating the risk of serious burns and potential permanent scarring with the use of Zecuity (sumatriptan iontophoretic transdermal system) patch for migraine headaches. Since marketing of the Zecuity patch began in September 2015, a large number of patients have reported experiencing burns or scars on the skin where the patch was worn. The reports included descriptions of severe redness, pain, skin discoloration, blistering, and cracked skin. As a result, FDA is investigating these serious adverse events to determine whether future regulatory action is needed, and will update the public with new information when the FDA review is complete.

Recommendation: Patients who experience moderate to severe pain at the Zecuity patch site should immediately remove it to avoid possible burns or scarring, regardless of how long the patch has been worn, and contact their health care professional. Patients should not bathe, shower, or swim while wearing the patch. Patients should read the Patient Information leaflet and the Instructions for Use section in the drug label, and talk with their health care professional if they have any questions or concerns.

Health care professionals should advise patients who complain of moderate to severe pain at the application site to remove the Zecuity patch immediately. Consider a different formulation of sumatriptan or switch these patients to an alternative migraine medicine. Evaluate patients and the application site as needed.

Loperamide (Imodium): Drug Safety Communication — Serious Heart Problems with High Doses from Abuse and Misuse

Issue: FDA is warning that taking higher than recommended doses of the common over-the-counter (OTC) and prescription diarrhea medicine loperamide (Imodium), including through abuse or misuse of the product, can cause serious heart problems that can lead to death. The risk of these serious heart problems, including abnormal heart rhythms, may also be increased when high doses of loperamide are taken with several kinds of medicines that interact with loperamide.

The majority of reported serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria. FDA continues to evaluate this safety issue and will determine if additional FDA actions are needed.

Recommendation: Health care professionals should be aware that use of higher-than-recommended doses of loperamide can result in serious cardiac adverse events. Consider loperamide as a possible cause of unexplained cardiac events including QT interval prolongation, torsades de pointes or other ventricular arrhythmias, syncope, and cardiac arrest. In cases of abuse, individuals often use other drugs together with loperamide in attempts to increase its absorption and penetration across the blood-brain barrier, inhibit loperamide metabolism, and enhance its euphoric effects. If loperamide toxicity is suspected, promptly discontinue the drug and start necessary therapy. If loperamide ingestion is suspected, measure blood levels, which may require specific testing. For some cases of torsades de pointes in which drug treatment is ineffective, electrical pacing or cardioversion may be required. Refer patients with opioid use disorders for treatment.

Patients and consumers should only take loperamide in the dose directed by their health care professionals or according to the OTC Drug Facts label. Patients should not use more than the dose prescribed or listed on the label, as doing so can cause severe heart rhythm problems or death.

Over-the-Counter Antacid Products Containing Aspirin: FDA Drug Safety Communication — Serious Bleeding Risk

Issue: The FDA is warning consumers about the risk of serious bleeding when using nonprescription, also known as over-the-counter or OTC, aspirin-containing antacid products to treat heartburn, sour stomach, acid indigestion, or upset stomach. Many other products for these conditions are available that do not contain aspirin.

These widely used products already contain warnings about this bleeding risk on their labels; however, we continue to receive reports of this serious safety issue. As a result, we will continue to evaluate this safety concern and plan to convene an advisory committee of external experts to provide input on whether additional FDA actions are needed.

Recommendation: Consumers should always read the Drug Facts label carefully when purchasing or taking an OTC product to treat heartburn, acid indigestion, or sour or upset stomach. If the product contains aspirin, consumers should consider whether they should choose a product without aspirin to relieve their symptoms.

Aspirin is a commonly used pain reducer and fever reducer. It is a nonsteroidal **anti-**inflammatory drug (NSAID) that can increase the risk of bleeding, including in the stomach and gastrointestinal (GI) tract. Consumers should ask their pharmacist if they need help reading the Drug Facts label.

Product updates

Drug	Indication	Mechanism of action (MOA)	Usual dose	Dosage forms and strength
Adlyxin®	Improve glycemic control in T2DM.	GLP-1 receptor agonist. Increases glucose-dependent insulin release, decreases glucagon secretion, and slows gastric emptying.	Usual starting dose is 10 mcg subcutaneously SQ once daily for 14 days. Increase the dose to the maintenance dose of 20 mcg once daily starting on day 15.	Subcutaneous injectable pen 50 mcg/mL in a 3 mL solution in a green single-patient use prefilled pen (for 14 doses at 10 mcg/dose) 100 mcg/mL in a 3 mL solution in a burgundy single-patient use prefilled pen (for 14 doses at 20 mcg/dose)
Xiidra®	Treatment of the signs and symptoms of dry eye disease (DED).	Binds to LFA-1, a protein found on leukocytes, and blocks the interaction of LFA-1 with ICAM-1.	Instill one drop of Xiidra twice daily into each eye using a single-use container.	Eye drops, 5%
Epclusa®	Treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.	Combination of sofosbuvir and velpatasvir, which are direct-acting antiviral agents against the hepatitis C virus.	One tablet taken orally once daily with or without food.	One tablet contains 400 mg of sofosbuvir and 100 mg of velpatasvir
Ocaliva®	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.	Decreases the intracellular hepatocyte concentrations of bile acids by suppressing de novo synthesis from cholesterol and by increased transport of bile acids out of the hepatocytes.	Starting dosage 5 mg orally once daily Maximum dosage 10 mg once daily	Tablets, 5 mg and 10 mg

References:

1. Adlyxin® [package insert]. Sanofil. July 2016.
2. Xiidra® [package insert]. Shire US Manufacturing Inc. July 2016.
3. Epclusa® [package insert].Gilead Sciences Inc. June 2016.
4. Ocaliva® [package insert]. Intercept Inc. May 2016.

Formulary additions

Drug	Indication	Mechanism of action (MOA)	Usual dose	Dosage forms and strength
Narcan®	Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.	Naloxone hydrochloride is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites.	For intranasal use only. Administer a single spray of Narcan® Nasal Spray to adults or pediatric patients intranasally into one nostril.	Nasal spray: 4 mg of naloxone hydrochloride in 0.1 mL
Breo Ellipta®	Indicated for: • Long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD). • Once-daily treatment of asthma in patients ages 18 years and older.	Breo Ellipta® contains both fluticasone furoate and vilanterol and the mechanisms of action for the individual components apply to Breo Ellipta®.	Maintenance treatment of COPD: one inhalation of 100/25 once daily. • Asthma: one inhalation of 100/25 or Breo Ellipta 200/25 once daily.	Oral inhalation: 100 mcg/25 mg Oral inhalation: 200 mcg/25 mg
Arnuity Ellipta®	Indicated for once-daily maintenance treatment of asthma as prophylactic therapy in patients ages 12 years and older.	Fluticasone furoate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Fluticasone furoate has been shown in vitro to exhibit a binding affinity for the human glucocorticoid receptor that is approximately 29.9 times that of dexamethasone and 1.7 times that of fluticasone propionate. The clinical relevance of these findings is unknown. The precise mechanism of corticosteroid action on asthma is not known.	Treatment of asthma in patients ages 12 years and older: one inhalation of Arnuity Ellipta® 100 mcg or 200 mcg once daily. Starting dosage is based on prior asthma therapy and disease severity.	Oral inhalation: 100 mcg Oral inhalation: 200 mcg
Anoro Ellipta®	Indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).	Since Anoro Ellipta® contains both fluticasone furoate and vilanterol and the mechanisms of action for the individual components apply to Anoro Ellipta®.	Maintenance treatment of COPD: one inhalation of Anoro Ellipta® once daily.	Oral inhalation: 62.5 mcg/ 25 mcg
Diclegis® (with prior authorization)	Indicated for the treatment of nausea and vomiting during pregnancy in women who do not respond to conservative management.	The MOA of Diclegis® is unknown.	Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one mid-afternoon, and two at bedtime).	Tablets: 10 mg/10 mg

*** = Only the generic equivalent of this product will process at the point of sale.**

References:

1. Narcan Package Insert. http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.
2. Breo Ellipta Package Insert. Revised July 2016. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Breo_Ellipta/pdf/BREO-ELLIPTA-PI-MG.PDF.
3. Arnuity Ellipta Package Insert. Revised November 2014. https://www.gsksource.com/pharmacontent/dam/GlaxoSmithKline/US/en/Prescribing_Information/Arnuity_Ellipta/pdf/ARNUITY-ELLIPTA-PI-PIL.PDF.
4. Anoro Ellipta Package Insert. Revised February 2016. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Anoro_Ellipta/pdf/ANORO-ELLIPTA-PI-MG.PDF.
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The Quarterly Pharmacy and Therapeutics Newsletter

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The formulary is updated quarterly. We recommend adding this link as a favorite in your computer's Web browser for easy access.