Updated Guidance by the CDC and FDA for Prescribing Opioids

June 30, 2023

In recent months, both the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) have issued updates related to the prescribing of opioids.

On November 4, 2022, the CDC issued the Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022, updating their previous recommendations published in 2016. The updated CDC guideline applies to outpatients 18 years of age or older with acute pain (duration of <1 month), subacute pain (duration of 1–3 months), or chronic pain (duration of >3 months), and excludes pain management for sickle cell disease, cancer-related pain, palliative care, and end-of-life care. Individualized, person-centered care should be supported using a multimodal and multidisciplinary approach.

The following key recommendations are included in the updated clinical practice guideline:

- Maximize the use of nonopioid therapies when possible and only consider opioids if the benefits of therapy are expected to outweigh the risks. Many nonopioid therapies (including nonpharmacological interventions) are at least as effective as opioids for common types of acute pain.
- Before starting opioids for pain, establish realistic treatment goals and discuss a plan for discontinuation if the expected benefit is not realized.
- If opioid therapy is indicated, an immediate-release product is preferred. Reserve long-acting or extended-release opioids for severe, continuous pain.
- When opioids are initiated in opioid-naïve individuals with acute, subacute, or chronic pain, prescribe the lowest effective dosage for no longer than the expected duration of pain severe enough to require opioids. Evaluate the potential benefits and risks when considering an increase in dose.

- Clinicians and patients should jointly weigh the benefits and risks of continuing opioid therapy. Relevant strategies to mitigate risk should be employed, including offering naloxone and reviewing potential interactions with any other prescribed medications or substances used.
- If the benefits of continued opioid therapy do not outweigh the risks, clinicians should optimize other therapies and work closely with patients to gradually taper to a lower dose.
- Unless there are warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), clinicians should not rapidly reduce opioid dosages from higher dosages or discontinue therapy abruptly.

In addition, on April 13, 2023, the FDA announced they would be requiring new safety label changes for both immediate-release (IR) and extended-release/long-acting (ER/LA) opioid analgesics. For a comparison of the more significant label updates included in this action, providers can refer to the Key Opioid Label Updates, which are included in the safety communication.

These updates also include a new warning about opioid-induced hyperalgesia (OIH), which is a condition where opioids cause an increase in pain or an increased sensitivity to pain. The safety label will now include information describing symptoms that differentiate OIH from opioid tolerance and withdrawal. If a patient is suspected to be experiencing OIH, the following recommendations are provided for health care providers:

- Carefully consider an appropriate decrease in dose of the current opioid pain medicine or safely switching them to a different opioid product, if tolerated.
- Advise patients about the risk of OIH and tell them to never increase the opioid dosage without first consulting a health care professional, because this could worsen the pain and increase the risk of respiratory depression.

To read the full safety announcement, refer to "FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use," which can be found on the Drug Safety and Availability page of the FDA's website.