



PROVIDER *bulletin*

July 3, 2018

Dear Provider:

The misuse of opioids has been chronicled nationwide. The prevalence is pervasive to all demographics, young and old, rural and urban, male and female, rich and poor, and any other way one wishes to stratify members. The problems can be seen with intentional misuse and unintentional as well.

Modifications

KFHC is incorporating expert opinion in developing appropriate opioid coverage for our members. Utilizing guidance statements from professional societies and providers in various practice settings locally, KFHC is developing a pain benefit that is structured to cover appropriate use of opioids. It includes adding other treatment modalities as needed. Cancer patients will continue to receive their medically necessary drugs. Opioids will be available to surgical patients as well. Appropriate opioid therapy will be available for members with chronic pain that have been worked up as well. Changes that may be seen that fall within consensus statements of the professional societies are: 1) New opioid starts will be limited to 7 days. 2) Evaluate why members are on chronic regimens. 3) Evaluate safe opioid regimens (elderly, high MEDD, combo w/sedative, bz, muscle relaxants, use in members with impaired respiratory conditions such as sleep apnea) and 4) Consider other therapy options: evaluate the member and the member's condition to determine if opioids, non-opioid, and even non-pharmacological methods are warranted.

KFHC covers other options for management of chronic pain. Acupuncture, chiropractic services, physical therapy, yoga, cognitive behavior therapy, psychoeducational, and addiction referral, if necessary, including Medication-Assisted Treatment (MAT) are all available to our members. Naloxone is available without authorization. Drug disposal lock boxes for proper handling of destruction of unused/unnecessary prescriptions are available throughout the county. These can be found at the following locations: North Chester Pharmacy, Your Drug Store, El Tejon on Chester, Komoto Pharmacy (Delano), CVS Bakersfield (Ming Ave), Arvin, Lamont, and Walgreens Bakersfield (Hageman, Mt. Vernon). El Tejon Brundage and Komoto Medical Pharmacy are scheduled to have boxes in the near future.

KFHC wishes to help provide availability and use of all the modalities needed to properly manage chronic pain, and to do so in a safe manner. Please see the CDC's guidelines, which follow this bulletin, for reference. More background information and a PDF version may be found at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>. The CHCF best practice guidelines are also included at the end of this bulletin.

Background

Kern Family Health Care strives to provide safe, quality care to its members in accordance with current evidence based guidelines. KFHC has formed a coalition of local providers to incorporate these best practices. The coalition consists of the following local multidisciplinary specialties: PCP, pain specialist, social worker, pharmacist, addiction counselor, in addition to collaborating with county mental health. The Centers for Disease Control (CDC), American College of Physicians (ACP), American Academy of Neurology (AAN), American Dental Association (ADA), Official Disability Guidelines (ODG), Collaborating & Acting Responsibility to Ensure Safety

(C.A.R.E.S) Alliance, and others have issued guidance statements regarding appropriate use of opioids for specific conditions. DHCS has issued guidance statements regarding appropriate use of opioids as well. The California Health Care Foundation (CHCF) is also coordinating efforts across the state to help manage the crisis. Evidence of the problem can be witnessed by the following statements.

- * Approximately 15,000 deaths occur every year involving prescription opioids.
- * 1 in 20 people in the US over the age 12 admitted to using pain killers for nonmedical reasons in 2010.
- * Enough prescription opioids were prescribed in 2010 to medicate every American adult in 2010 around the clock for a month.
- * 20% of the prescribers prescribe 80% of the opioids.¹

* KFHC's stats:	<u># Rx/year</u>	<u># of units/year</u>
2016	79,000	3,900,000
2017	76,000	3,800,000

Safe and appropriate use of opioids, or any medication for that matter, requires diligence on everyone's part: health plan, physicians, nurses, pharmacists, dentists, members, and the community as a whole. It is not just the responsibility of the pain specialist. The member's overall health must be always at the forefront. There has been great emphasis in the past to treat pain as the fifth vital sign. Although it is important to address that one component, it is wise not to put too much emphasis on that area alone and neglect the aspect of managing the whole person. Many organizations: state legislatures, health plans, professional societies, and others are now calling for more limited approaches on dispensing opioids, particularly in combination of other medications. However, medicine, and society, must be careful not to vacillate between the two extremes, but to find a more centrist approach encompassing sound medical practices. This may involve patience, multiple disciplines, and different treatment modalities. It will most likely include member education to help them rethink and accept what was a standard of practice.

Opioids have a place in medicine. One cannot simply state that they are bad and there is never a right time for their use. Yet, one cannot take the opposite approach and simply ignore that there is never a danger. One must be cognizant of the benefits and risks of any opioid therapy and be willing to modify the therapy when those risks begin to outweigh the benefits and/or the functional goals are not being met. One has to be aware of goals of short-term, acute pain and the corresponding role of opioids, as well as the goals of long-term management of chronic pain and the role opioids play in that scenario.

Acute pain is defined by the American College of Physicians as therapy lasting less than 3 months. Remodeling of the brain neurons may take place in much less time. This remodeling may be seen in as short as 14 days. The more problematic task is managing non-malignant chronic pain and trying to prevent the conversion of acute to chronic pain.

Each day in the United States, 46 people die from an overdose of prescription opioid or narcotic pain relievers.² The Centers for Disease Control and Prevention (CDC) describe the following groups as particularly vulnerable to prescription opioid overdose: 1) those who obtain multiple controlled substance prescriptions from multiple providers; 2) those who take high daily dosages of prescription painkillers and those who misuse multiple abuse-prone prescription drugs, especially other CNS depressants, such as benzodiazepines, carisoprodol, or other sedatives; 3) low-income people and those living in rural areas; and 4) those with mental illness and/or a history of substance abuse.³

One of the confounding issues with chronic pain management is the occurrence of opioid-induced hyperalgesia. Opioid-induced hyperalgesia (OIH) is defined as a state of nociceptive sensitization caused by exposure to opioids. The condition is characterized by a paradoxical response whereby a patient receiving opioids for the treatment of pain could actually become more sensitive to certain painful stimuli. The type of pain experienced might be the same as the underlying pain or might be different from the original underlying pain. OIH appears to be a distinct, definable, and characteristic phenomenon that could explain loss of opioid efficacy in some patients.

The precise molecular mechanism of OIH, while not yet understood, varies substantially in the basic science literature, as well as in clinical medicine. It is generally thought to result from neuroplastic changes in the peripheral and central nervous system (CNS) that lead to sensitization of pronociceptive pathways.

Clinicians should suspect OIH when the effect of an opioid treatment seems to wane in the absence of disease progression, particularly if found in the context of unexplained pain reports or diffuse allodynia unassociated with the original pain, and increased levels of pain with increasing dosages. The treatment involves reducing the opioid dosage, tapering them off, or supplementing with NMDA receptor modulators.⁴

KFHC sees using a multi-modal approach in managing its members with non-malignant chronic pain to prevent converting acute pain members on opioids to those with chronic pain or at the very least prevent escalating opioid use or the use of more risky opioids. These actions may pose a paradigm shift in how non-malignant pain is to be managed. An example of this re-thinking can be seen by a study conducted by gynecological oncologists in New York. It was shared at the 2018 Society of Gynecologic Oncology Annual Meeting. The hypothesis was that surgeons overprescribe opioids for those undergoing major and ambulatory surgeries. The study looked at the member pain satisfaction afterwards. "Members in the study received a 73% decrease in the number of tablets typically prescribed for those undergoing surgery until that point, and a 97% decrease for those who had ambulatory or minimally invasive procedures. Over 90% of those undergoing minimally invasive procedures received no opioids at all. The study observed no difference in postoperative pain scores and patient satisfaction. Implementation of an ultra-restrictive opioid prescription protocol decreased the opioids dispensed in chronic opioid-use patients by 83%, and opioid refills remained low."⁵

Another study by Dr. Erin Krebs, published in the March 6, 2018 edition of JAMA, showed the effectiveness of opioid vs non-opioid medications on pain-related function with chronic back, hip or knee osteoarthritis. The findings determined that there was no significant pain-related functionality between the opioid and non-opioid groups after 12 months.⁶

Low back pain is one of the diagnoses that often results in opioid prescriptions, however, the recommendations from the American College of Physicians do not support this treatment for initial management.

Recommendation 1: *Given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacological treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence). (Grade: strong recommendation)*

Recommendation 2: *For patients with chronic low back pain, clinicians and patients should initially select nonpharmacological treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation)*

Recommendation 3: *In patients with chronic low back pain who have had an inadequate response to nonpharmacological therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients. (Grade: weak recommendation, moderate-quality evidence)⁷*

In fact, more intensive work up is desired to properly identify the cause as many cases of low back pain may be best managed by other modalities. A consensus statement from the ACP and American Pain Society supports this.⁸

Some modifications really just provide limited benefit, such as removing coverage of high strength opioids, methadone (for pain management, not MAT), MEDD, and quantity limits. To properly and appropriately address non-malignant chronic pain and begin to remove unnecessary doses of opioids on a large scale, management of chronic pain has to incorporate other modalities.

Some disease states that are more neuropathic than nociceptive in nature are probably not good candidates for opioid therapy, at least in the initial stages of management. Conditions such as fibromyalgia, diabetic neuropathy, and other neuropathic presentations are a few examples.

Screening Tools

Common screening tools to assess appropriateness of opioid therapy are attached. Tools to assess the initiation and/or continuation of opioid therapy include: Webster's Opioid Risk Tool (ORT), National Institutes of Drug Abuse (NIDA), Pain Assessment and Documentation Tool (PADT), and Current Opioid Misuse Measure (COMM). Others are available as well. A tool to evaluate the risk of overdose or respiratory depression is the Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD).

Summary

KFHC appreciates your care for our members. We appreciate your engagement in reducing opioid-induced adverse effects and/or deaths. Your partnership and cooperation in adopting and fully utilizing all modalities to manage non-malignant chronic pain, such as initial pain scripts for 7 days or less, evaluating chronic therapy for appropriateness and risk, and consideration of other treatment options, including non-pharmacological ones, is valued and respected.

Sincerely,

Bruce Wearda, R.Ph.
Director of Pharmacy

1. CDC Website <http://www.cdc.gov/homeandrecreationalafety/rxbrief/>
2. Centers for Disease Control and Prevention. Vital signs: opioid painkiller prescribing. July 2014. Available at: <http://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.pdf>. Accessed: August 13, 2015.
3. Centers for Disease Control and Prevention. Policy impact: prescription painkiller overdoses. Available at: <http://www.cdc.gov/drugoverdose/pdf/policyimpact-prescriptionpainkillerod-a.pdf>. Accessed: August 13, 2015.
4. Pain Physician 2011; 14:145-161.
5. Targeted Oncology; March 25, 2018.
6. JAMA. 2018;319(9):872-882.
7. Ann Intern Med. 2017;166(7):514-530.
8. Am fam Physician 2008 Jun 1;77(11):1607-1610.