

### Q&A Summary U.S. Opioid Epidemic: Mitigation and Treatment Opportunities

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What about safety regarding filling opioid prescriptions? The street value of such drugs is about \$25/pill.

Any prescription ordered by a provider will be based on state and federal laws. Regarding diversion, that would be out of scope for the medical provider, pharmacist/pharmacy, Pharmacy Benefit Management (PBM) or case management services.

Please address this issue: Last year, my grandson had his wisdom teeth extracted. He was prophylactically prescribed Norco, 1 tab Q4-6h for breakthrough pain; 20 total tabs given (7.5 hydrocodone + 325 acetaminophen). He did NOT take it. He was experiencing no real pain, he said, and only took Motrin 800 on the first day. Why is this acceptable practice?

Individuals respond uniquely to pain. As currently ordered, if taken at the maximum six times per day, this equates to 45 Morphine Milligram Equivalent (MME), which is below current Center for Disease Control and Prevention (CDC) recommendations. Also taken at this maximum frequency, the supply would last for three days with two additional pills left over, thus also fairly close to CDC recommendations to limit short-acting opioids Rx for acute pain to three days or less. Often the provider will recommend taking a nonsteroidal pain med such as ibuprofen (Motrin®) if this adequately controls pain instead of an opioid; yet the opioid is available if needed.

## Pharmacy plans need to allow nonopiate meds like lidocaine patches that work for members. I know of people who've been put on opiates because the patches are no longer covered.

Pharmacy plan coverage of medications including topical analgesics such as lidocaine patches is determined on an individual client/plan basis. The member should verify the coverage of each medication with their pharmacy benefit plan including any plan limitations, prior approval requirements and out-of-pocket cost expectation. For additional assistance of clinical options, referral to a clinical pharmacist (or medical director if the pharmacist is not available) should be considered to review the member's clinical situation and provide options for members to discuss with their medical provider.

I thought all pharmacies had to alert a doctor if an alert shows?

Pharmacists dispensing prescription medications may receive electronic messages from the pharmacy benefit manager at the time of adjudicating the Rx claim alerting them of potential concerns with a specific member and his/her medication. The pharmacist evaluates these messages and, based upon clinical knowledge and critical thinking skills, determines actions that may be needed including discussion with the patient and/or reaching out the prescribing medical provider if/when necessary or appropriate.

### Please address tramadol as a risk of opioid abuse.

Tramadol should place individuals at the same risk as any other opioid based on the dosage and duration. Note that 50 mg of tramadol is only five (5) MME. "Tramadol is a centrally acting analgesic with a unique, dual mechanism of action. It is a mu-opioid receptor agonist and a weak inhibitor of norepinephrine and serotonin reuptake. ... Tramadol is a synthetic analog of codeine; however, tramadol has a lower affinity for opioid receptors than codeine. Tramadol has less potential for abuse or respiratory depression than other opiate agonists, but both may occur. Drug abuse and overdose, seizures, serotonin syndrome, suicides, and anaphylactoid reactions have been associated with tramadol use/misuse. Due to CYP2D6- and CYP3A4-dependent tramadol metabolism, potentially serious drug interactions are possible."\*

\**Clinical Pharmacology*. Tramadol Monograph. Accessed 05/24/2018 http://www.clinicalpharmacology-ip.com

## Since chronic opioid therapy is not an option for chronic pain, why is it so difficult to get alternative treatment therapies approved such as massage, acupuncture, etc.?

Approval of individual therapies will be based on certificate of coverage that the member has available to them. Some therapies may not have undergone adequate peer review to warrant including based on medical necessity.

### What are the alternatives for individuals with chronic pain in general, other than antidepressants/anticonvulsives that don't work for everyone?

There are multiple alternate options for chronic pain, including diet, hormone replacement, and socialization. Please refer to the slide "treatment of chronic pain" in the presentation.

### What should we tell people to use for pain relief?

For acute pain, use the lowest dose of treatment for the shortest period of time consistent with CDC guidelines if considering opioids. Chronic pain: see answer above.

## I see a lot of people now being managed with tramadol. How does this compare with addiction risk?

Answered prior.

What about the use of dextromethorphan as it is an opioid blocker? Patients that are using opioids and have it in their cough syrup are susceptible to overdose.

"Dextromethorphan is an oral, nonopioid, nonprescription drug used as an antitussive. Although it is related to the opiate agonists (dextromethorphan is the methyl ether of the d-isomer of the codeine analog levorphanol), dextromethorphan does not exhibit typical opiate agonist characteristics. The only morphine-like characteristic dextromethorphan retains is its antitussive property... When ingested at recommended dosage levels for intended purposes, dextromethorphan is generally regarded as a safe and effective cough suppressant.

"On May 20, 2005, the FDA made a public announcement regarding dextromethorphan (DXM) and new trends in the abuse of this drug. The ingestion of pure dextromethorphan in powdered form and in excessive doses can cause death as well as other serious adverse events such as brain damage, seizure, loss of consciousness, and irregular heartbeat. Although the reported abuse of dextromethorphan is not new, dextromethorphan is increasingly offered for sale in pure powdered form from questionable sources (e.g., unsanctioned pharmacy websites) and street dealers, and health care professionals should be alert to these new trends."\*

\**Clinical Pharmacology*. Dextromethorphan Monograph. Accessed 05/24/2018 http://www.clinicalpharmacology-ip.com

#### How soon does someone become addicted to opioids?

From presentation: "After taking opioids for just five (5) days in a row, a person is more likely to take them long-term."

## With the changes to the allowed amount of opioids, how do we avoid people having withdrawals because they run out of medications while waiting for the prior authorization (PA) to be approved?

For members currently prescribed opioid analgesic dosages exceeding plan limitations, pharmacy benefit plans usually allow a transitionary supply of medication. Members and prescribers are notified of limitations with adequate time for transition and adjustment to treatment plans including tapering down opioid analgesic daily dosage requirements. Members and providers should proactively work with the pharmacy benefit plan PA process to ensure compliance with the requirements for ongoing utilization of opioid analgesics.

### Do you see nurses working more as case managers to oversee the progress and management of members who take opioids?

This is a trend that may continue based on the demographics of opioid use disorder.

### What nonopioid pain medications besides Tylenol or NSAIDS are available?

Alternatives to opioid analgesics for pain management depend on the type, severity and location of the pain. At this time, oral options with direct analgesic effects include acetaminophen, NSAIDs and opioid analgesics. Adjuvant therapies such as skeletal muscle relaxers, anti-convulsants (e.g. gabapentin), antidepressants (e.g. duloxetine) as well as topical analgesics (e.g. lidocaine, capsaicin) or localized injectable anesthetics may be considered depending on the individual clinical situation.

#### What are your thoughts on Rx genetic testing to aid providers in prescribing?

Interesting concept; unsure if there is any data to support.

### Member taking Suboxone for dependence but the pharmacy was receiving a limited supply and needed to call different pharmacies. Can you talk about the med used to help with her addiction. She was found to have an allergy to narcan.

Suboxone® (synthetic opioid) therapy should be part of medication-assisted treatment (MAT).

#### Cannabidiol (CBD) oil is becoming very popular.

Cannabidiol oil (CBD): Produced without regulation and unclear scientific benefits to date.

### What about marijuana for chronic pain? Do you see that becoming more of an option for members?

This is a growing science, and I suspect there will be more to come on the topic. However, at this time, usage is unregulated, unapproved by the FDA and prohibited by federal law as a DEA class 1 controlled substance.

### Is the long-term use of narcotics causing individuals to experience chronic pain syndromes?

From the presentation: "Chronic pain and opioid addiction are similar in effects on autonomic nervous and endocrine system."

Do you have any helpful suggestions on ways to handle members who NEED the medications vs. those that WANT the medication? With all of the regulations being placed, it is getting very difficult for those that truly need the medication and pain is becoming uncontrollable.

If the member desires to use health benefits, they will be limited by those particular rules and regulations. If requested dosage is higher than allowed per policy, a prior authorization process would be required.

### Which medication is most effective for recovery — Naltrexone or Suboxone?

Per National Institute on Drug Abuse (NIDA), both are equally effective when used as opiateaddiction-treatment medications.

#### Where can people dispose of unused prescription opioids?

There may be local places to drop off unused drugs in an individual's community. They can call their local pharmacy, plus can follow United States Food and Drug Administration directions, which are available for review. In addition, disposal of unused medications including opioids has been reviewed in the April 2018 Edition of our Optum Clinical Pharmacy newsletter "The Capsule (Pharmacy Newsletter)" located on the Optum Clinical Knowledge Platform Share Point <u>http://ckp-sp.optum.com/SitePages/Home.aspx</u>

### How close are we in developing drug testing likened to the A1C that gives us a window of usage to assist in pain management?

Currently there are various testing available that can show usage based on half-life of the medication and elimination from the body. Sources can be urine or hair.

### We all know that withdrawal is extremely dangerous, why do insurances not pay for treatment clinics in order to help resolve addictions?

That would be based on and individual's health plan certificate of coverage.

Some of the safeguards in place to control opioid abuse by the PBM appear like very sound strategies to mitigate the opioid abuse epidemic in this country. However, a recent report analyzed by CNN and Harvard University found that there was strong correlation between pharmaceutical companies paying out to providers prescribing opioids. It is unclear if the payout to doctors resulted in more opioids from a particular manufacturer or if that manufacturer sought out providers who prescribed a lot and compensated them. How will we address this barrier?

Many states in the U.S. now have mandatory programs in place regarding continuing education of providers as well as monitoring practices. Consumers always have the option of asking the provider if the drug is truly necessary or if a generic form is available.

#### What are long-term dangers of Medication Assisted Treatment (MAT)?

The individual is still taking an opioid medication and exposed to the risks of the medication itself.

### What about providing access to pain management programs using mindfulness, preventing triggers, utilizing good body mechanics, and psychotherapy?

These are all good options and would be limited based on the member's certificate of coverage regarding benefits.

## Alternative therapies can sometimes help with chronic pain (acupuncture, etc.). Are insurances looking into expanding coverage for alternative therapies? Alternative therapies may help reduce the prescriptions written for opioids!

All good suggestions. Similar to above, coverage is based on benefit language.

### If an individual is not using a PBM is there a way to track the individual's use of pain medications?

If buying drugs legally, you can check state prescription drug monitoring program (PDMP). PDMP are available in all states except Missouri at this time. Access to these databases is regulated and granted by individual states to prescribers and pharmacies and because of PHI are not available for public use.

# In addition, there appears to be pushback from providers regarding Medicare guidelines that gives pharmacists the ability to deny opioid prescriptions. Will this barrier affect the strategies being employed to control opioid abuse?

Medicare has specific policies related to opioid prescribing, including quantity and day-supply limitations that are determined by CMS. Medicare recently released a proposal for 2019 regarding opioid usage with the main point being hard stop of seven-or-fewer-days supply of opioids for opioid-naïve/new opioid prescriptions and implementation of a safety alert when MME > 90mg/day. Additional information regarding this proposal can be found at <a href="https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html">https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html</a>

## Besides CNS depressant, there is a lot of talk of neurological deficits. Could you mention a few of them?

The human brain makes its own small amount of opioid. When taking an opioid as medication, this increases multiple-fold, leading to an increase in dopamine. Effects can be euphoria/pleasure, blockage of pain, decreased respiratory drive. Another effect can be development of nausea/vomiting.

### There is obviously a lot of work being done from the supply side. What is being done to alleviate issues from the demand side of the equation?

Per CDC guidelines from 2016, initial prescription for pain management should provide the lowest dose for the shortest possible period; preferably less than 50 MME x three days. Following this recommendation will help mitigate development of tolerance to the drug that eventually leads to individuals becoming addicted to opioids. For those with substance use disorder, MAT can assist.

## People are ordering these drugs via computer from various countries. This also needs to be addressed.

Obtaining any medication internationally is not regulated, and individuals are at risk of violation of federal laws including controlled substance trafficking if attempting to procure substances regulated by the federal DEA including opioids. In addition to criminal legal risk, medications obtained internationally are oftentimes counterfeit and/or contaminated with dangerous substances. Obtaining medications internationally should be discouraged other than with a medical provider's prescription and following local and federal laws and regulations.

### Doesn't the shared responsibility fall on the pharmacist also?

As per the final slide in the formal presentation, responsibility falls on all of us (members, providers, government, manufacturers, health plans, PBMs and the general public).

How about developing a pain management plan prior to sending someone home with any pain pills such as a goal of three or less (a score of four–six on a pain scale warranting an OTC and seven–10 warranting a narcotic). Members should be told what to expect, and for what and when to notify a physician.

CDC does recommend assessing pain and function:

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average three individual question scores (30 percent improvement from baseline is clinically meaningful)

Q1: What number from 0–10 best describes your pain in the past week?

0 = "no pain," 10 = "worst you can imagine"

Q2: What number from 0–10 describes how, during the past week, pain has interfered with your enjoyment of life?

0 = "not at all," 10 = "complete interference"

Q3: What number from 0–10 describes how, during the past week, pain has interfered with your general activity?

0 = "not at all," 10 = "complete interference"

CDC also recommends discussing benefits and risks as well as risk of harm or misuse.

### How do we tell if someone is suffering from chronic pain from person who wants to get high?

This is too detailed to quickly answer as it will depend on history, physical exam and full patient assessment.

### What is being done to the pharmaceutical companies that have developed these opioids?

Purdue Pharma was fined over \$600 million in fines for false promotion; three executives pleaded guilty to criminal charges.

### Are there herbal medicines that have opioid type effects?

Herbal (dietary supplements) are unregulated, have limited safety and efficacy information, and very limited drug interaction information. There are no known evidence-based medicine (EBM) supported dietary supplements for management of pain.

### What about supplying Narcan kits?

Availability of Narcan® (Naloxone) in various formulations including nasal spray and autoinjectors, is currently being addressed in individual state laws and regulations. Naloxone is being made available to individuals prescribed opioids, their family members, the public, and first responders based on state pharmacy laws and regulations. Members on chronic opioids are at high risk of addiction and should be encouraged to discuss having Naloxone available; such a discussion should include education of their family and friends on usage and emergency response as outlined in the presentation.

### What role do our schools play in educating and empowering teachers in the fight against this epidemic?

A large role, but incorporating into curriculum would be based on acceptance via local school boards unless mandated via state or federal laws.

#### What age group is most likely to overdose?

From CDC:

Heroin: 25-35

Methadone: 45-55

Do you feel some physicians are now swinging too far the other way? Speaking to many members that have their pain managed only to be told "sorry, no more refills" without discussing a plan to move towards something out.

That may be possible. Suggesting MAT would appear to be a better solution.

What are your thoughts of educating and transitioning our members to another form of pain relief such as acupuncture in Eastern medicine?

In general, out of scope; to be addressed by a provider.

If a patient has cancer and has been given opioids and benzoids and is now in remission but were on multi-opioid prolonged therapy (I'm seeing more and more patients on oxycodone, oxycontin and methadone), how can we help these patients with addiction/weaning down? A lot of cancer is referred/being followed by pain management specialist.

#### MAT

### How are amphetamines useful?

Amphetamine can have analgesic effect, though prolonged use is not recommended due to development of tolerance.

### If excessive opiates are noted, should we involve MD director AND pharmacist?

Health plan policy will limit dosage. Higher doses may have been approved via PA process. Thus it is likely individuals on higher dosages will have already received prior approval. Any referral pattern should be based on standard job aid process.

### How do you see the use of virtual reality for pain management? If you would like information, I do know a Navy Seal that does have that product available.

Interesting concept, probably very similar to visualization therapy, but I do not know anything about it.

#### What pain meds can be taken for long-term pain?

Opioids are not recommended for long-term pain. See prior question "What nonopioid pain med besides Tylenol or NSAIDS is available?"

#### What is the rest of the world prescribing?

The rest of the world is typically not prescribing opioids. Part of this is bureaucratic and part is availability. In fact, worldwide, pain actually might not be treated adequately. The issue in the United States is the excessive overprescribing of opioids.

### You mention fibromyalgia, what about arthritis — RA, osteoarthritis, etc. Many members are on opioids for chronic pain.

It would be a similar approach.