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# **PRACTICING SAFER PAIN MANAGEMENT AND OPIOID CONVERSIONS**

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# DISCLOSURE

There are no conflicts of interest to disclose.

Disclaimer: The use of brand name medications is due to limited generic availability of buprenorphine treatment options and primarily for clinical reasons. The use of brand names does not represent any conflicts of interest or promotion of one pharmacological agent over another.

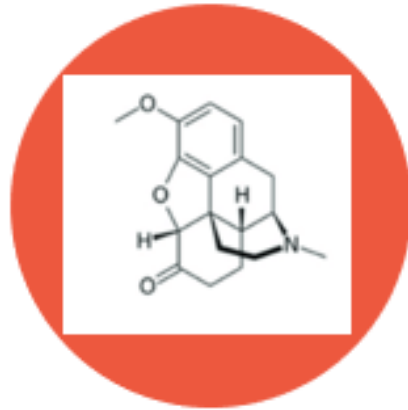


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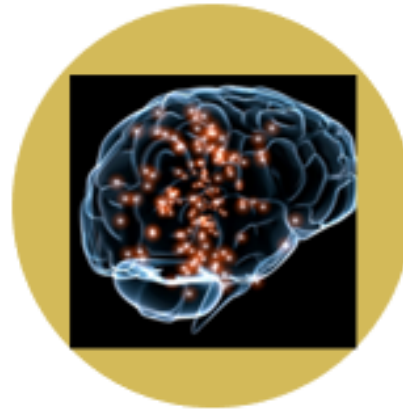
# OBJECTIVES

1. Understand risk stratification and monitoring of patients using opioid pharmacotherapy for chronic pain, especially in patients with opioid tolerance who may benefit from buprenorphine conversion.
2. Describe the statistics and treatment considerations for chronic pain, and its overlap with opioid use disorder (OUD).
3. Evaluate pharmacotherapeutic and integrative health options in pain and OUD management, including acupuncture and meditation.

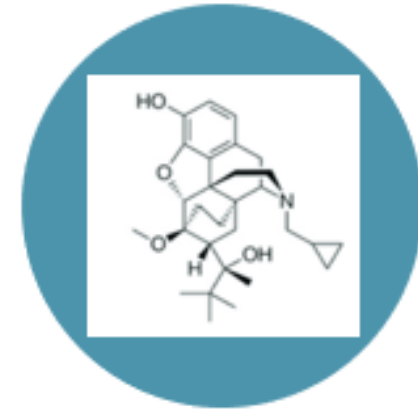
# RETHINKING CHRONIC PAIN RX



FULL OPIOID AGONIST.



CENTRAL PAIN PROCESSING  
& SENSITIZATION



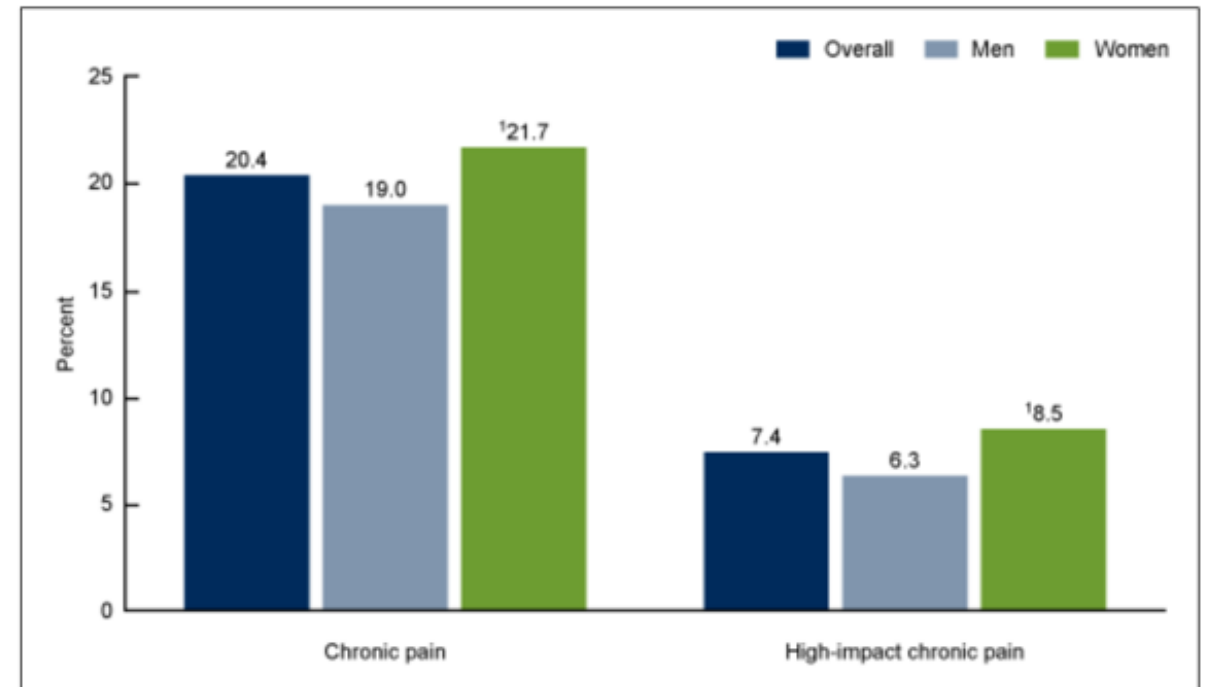
PARTIAL OPIOID AGONIST.

# CHRONIC PAIN STATS

❑ Overall, the prevalence of chronic pain was 20.4%, and the prevalence of high-impact chronic pain was 7.4%.

❑ Women were more likely to have chronic pain (21.7%) and high-impact chronic pain (8.5%) compared with men (19.0% and 6.3%, respectively).

Figure 1. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, overall and by sex: United States, 2019



# PAIN—ETYMOLOGY & FEATURES



❑ An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.

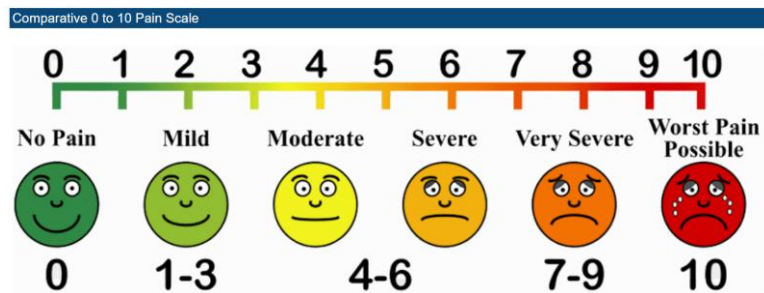
❑ Six key features:

- Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.
- Pain and nociception are different phenomena → Pain cannot be inferred solely from activity in sensory neurons.
- Through their life experiences, individuals learn the concept of pain.
- A person's report of an experience as pain should be respected.
- Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.
- Verbal description is only one of several behaviors to express pain; inability to communicate does not negate the possibility that a human or a nonhuman animal experiences pain.



# EVALUATING CHRONIC PAIN

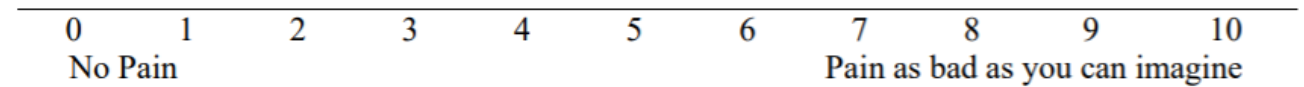
❑ Best evaluated using a validated assessment – don't just focus on the pain scale!



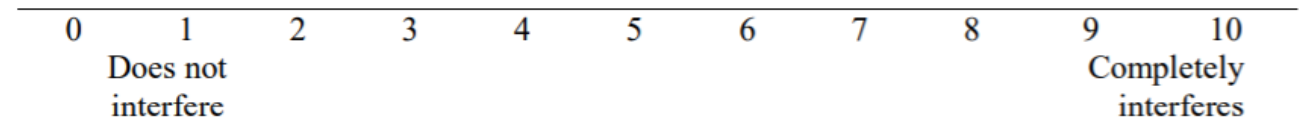
❑ Consider a PEG assessment:  
**P**ain – **E**njoyment – **G**eneral activity



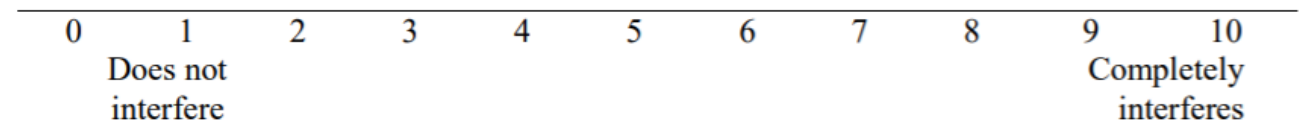
1. What number best describes your pain on average in the past week?



2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?



3. What number best describes how, during the past week, pain has interfered with your general activity?



# CLINICAL SCENARIO-1

HPI: 50 y/o male with pmhx of chronic LBP, migraines, shoulder arthritis/prior RTC injury, depression, AUD (partial remission), cocaine use disorder (partial remission) and daily cannabis use presents for an evaluation for chronic pain management. Reports having left-sided sciatica pain radiating behind down the left leg intermittently. Had an MRI the year prior to initial evaluation that demonstrated lumbar lordosis, alignment of body heights and facets, no signal abnormality, L4-L5 showed mild facet osteoarthritis, mild spinal stenosis and mild foraminal stenosis. Last injections were a decade ago. No prior surgical intervention for the spine. Pt admitted to buying illicit hydrocodone from the street 10/325mg BID and ibu 600mg TID with pain level of 5/10. Admits that he typically has diarrhea due to colitis, but denies any d/c. He admits to stopping both alcohol and cocaine 6 months “cold turkey” prior and lost 20 lbs (this was due to pressure from his wife due to his spending). Admits to craving alcohol; denies opioid cravings. He is interested in acupuncture. Was started on duloxetine 20mg daily two weeks ago and feels his pain and mood is slightly better. Denies SI/HI.

Examination reveals intact strength without any neurologic findings. No tenderness of the axial lumbar spine or paraspinals. Strength testing intact and symmetric DTRs. Dental: poor dental hygiene, missing some teeth, +dental implants

PDMP is consistent with self report. Urine toxicology: +opioids +THC





# CLINICAL SCENARIO-1: SCREENING & RISK ASSESSMENT

50 y/o M screenings reveal: PEG: 5/9/8 (avg. 7) on hydrocodone/APAP 10mg/325mg BID (illicit) + ibuprofen 600mg TID.

PHQ-9: 18  
GAD-7: 14  
AUDIT-C: ??  
ORT-R: ??

- ☐ What are the best treatment options for him?
- ☐ Does this patient meet criteria for OUD?



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# UNDERSTANDING OPIOID USE DISORDER

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# THE INTERSECTION OF CHRONIC PAIN & OPIOID MISUSE/USE DISORDER

- ❑ What is the prevalence of Opioid Misuse/Use Disorder (OUD) in patients who suffer with chronic pain?
- Unclear, as limited evidence, ambiguous terminology, conflicting results.
- A systematic review of 38 studies suggests patients with chronic pain:

**21% to 29% have opioid misuse**

**8% to 12% have OUD**



# RISK STRATIFICATION TOOLS & SCREENINGS

- ☐ SOAPP 8® *versus*
- ☐ Opioid Risk Tool - Revised
- ☐ Screen for Depression & Anxiety (PHQ9/GAD7)
- ☐ Screen for alcohol use disorder (AUDIT-C)
- ☐ Screen with Drug Abuse Screening Test (DAST-10)

## Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark Each Box That Applies

Yes No

Family history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Personal history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Age between 16-45 years	1	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	1	0
Depression	1	0
Scoring total		

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# THE NEUROBIOLOGY OF ADDICTION

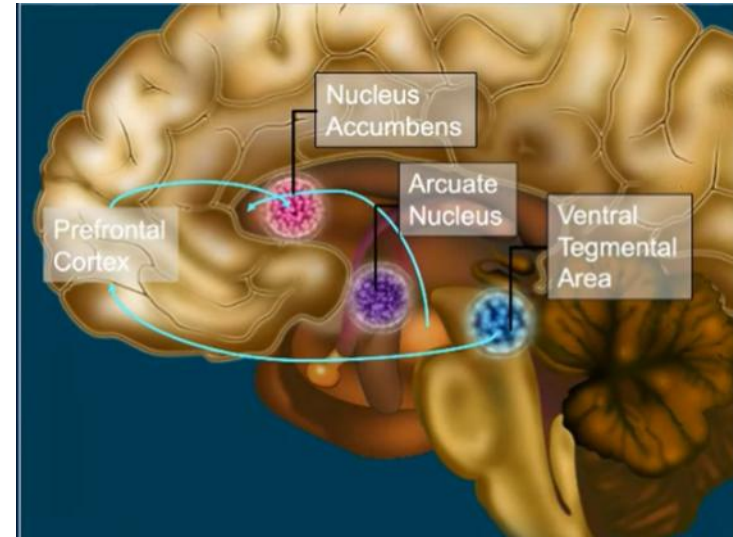
□Addiction is a chronic, relapsing disorder characterized by a compulsive drive to take a drug (or substance) despite:

- serious consequences
- Loss of control over intake
- And the emergence of a negative emotional state during abstinence

→leads to profound behavioral disruptions

→The NA and VTA are the pleasure/reward pathways of the brain are “hijacked” by substances.

→Drugs impact many neuronal circuits—processing rewarding stimuli, negative emotions, interoception, decision-making, and cognitive control—turns drug use into a compulsive behavior.





# DSM-5 CRITERIA - OUD

Severity level:

Mild: 2-3  
symptoms

Moderate: 4-5  
symptoms

Severe: 6 or more  
symptoms

- Loss of Control
  - Larger amounts, longer time
  - Inability to cutback
  - More time spent, getting, using, recovering
  - Activities given up to use.
  - Craving
- Physiologic
  - Tolerance
  - Withdrawal
- Consequences
  - Hazardous use
  - Social or interpersonal problems related to use
  - Neglected major roles to use
  - Continued use after significant problems.

- A substance use disorder is defined as having 2 or more of these symptoms in the past year
- Tolerance and withdrawal alone don't necessarily imply a disorder.
- Severity is related by the number of symptoms.

**2-3 = mild**  
**4-5 = moderate**  
**6+ = severe**



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# X WAIVER HAS BEEN ELIMINATED!

Feb. 10, 2023 (ACP) — Thanks in part to advocacy efforts by the American College of Physicians, the X-waiver requirement is history. Under the prior federal requirement, only doctors who received specialized training and federal permissions could prescribe buprenorphine to treat opioid addiction, which was a significant barrier to the treatment.

Language was included in the Consolidated Appropriations Act 2023, which became law on Dec. 29, that eliminated the requirement for health care practitioners registered to dispense controlled substances to apply for a separate waiver through the Drug Enforcement Administration (DEA) to dispense buprenorphine for opioid use disorder treatment, known as the X-waiver.

On Jan. 12, the Substance Abuse and Mental Health Services Administration and the DEA formally announced the elimination of the X-waiver. Now, any clinician with a current DEA registration that includes Schedule III authority can prescribe buprenorphine for opioid use disorder.



# MEDICATIONS TO TREAT OPIOID USE DISORDER (MOUD) AND PAIN



- ❑ ONLY requires a Drug Enforcement Agency (DEA) license!
- ❑ Referred to as Medication-assisted Treatment (MAT) → Medications for Opioid Use Disorder (MOUD)
- ❑ Buprenorphine/naloxone (Suboxone®, Zubsolv®) - FDA approved for treating OUD.
- ❑ Lower risk of abuse potential - contains both buprenorphine & naloxone.
- ❑ Naloxone is an opioid antagonist (Narcan® – an opioid overdose reversal agent which should be prescribed with any initial opioid treatment).
- ❑ Mechanism of action: partial opioid agonist therapy that binds to the pain receptors (mu receptors) with a safer profile. Caution: hypoxemia/COPD
- ❑ Greater acceptance of using buprenorphine/naloxone **OFF LABEL** for chronic pain.

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# CONSIDER EDUCATING PATIENTS ON DENTAL RISKS (ALL OPIOIDS CAUSE XEROSTOMIA)



**FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain**

*Benefits for use outweigh these risks and oral care can help*

**1-12-2022 FDA Drug Safety Communication**

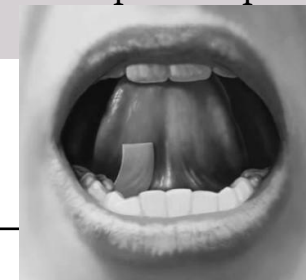
## **What safety concern is FDA announcing?**

The U.S. Food and Drug Administration (FDA) is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. Despite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks.

**Always document a baseline dental assessment: edentulism, periodontal disease, missing teeth, dental hygiene prior to Rx buprenorphine**

# FDA APPROVED BUPRENORPHINE\* FOR PAIN

Transdermal buprenorphine	Buccal Buprenorphine films	Buprenorphine/naloxone sublingual tabs/films
Marketed as Butrans® patch	Marketed as Belbuca®	*Buprenorphine/naloxone –is also used off label for pain management
Dosed every 7 days (patch rotation)	Dosed q12hrs	Dosed 2/0.5mg TID/QID for pain
MAX: 20mcg transdermal patch	MAX: 900mcg film	MAX: 8/2 mg TID (less common)
QTc prolongation, rash, N/V, lower the seizure threshold, respiratory depression	QTc prolongation, N/V, Can lower seizure threshold, respiratory depression	Elevated LFTs, nausea, headaches, lowers seizure threshold
\$305-\$810 *Requires Prior Auth	\$314-\$922 *Requires Prior Auth	\$119-\$289 *Monotherapy bupe requires Prior Auth, must designate ICD10 F.11.20 (OUD or opioid dependency)



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## Vertex Announces FDA Acceptance of New Drug Application for Suzetrigine for the Treatment of Moderate-to-Severe Acute Pain

*– FDA grants priority review and assigns a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2025 –*

*– Suzetrigine, an investigational non-opioid pain signal inhibitor, has the potential to treat millions of patients who suffer from moderate-to-severe acute pain each year –*

BOSTON--(BUSINESS WIRE)--Jul. 30, 2024-- [Vertex Pharmaceuticals Incorporated](#) (Nasdaq: VRTX) today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) submission for suzetrigine, an investigational, oral, selective NaV1.8 pain signal inhibitor to treat moderate-to-severe acute pain. Suzetrigine has the potential to be the first new class of medicine to treat acute pain in over twenty years.

The FDA has granted suzetrigine priority review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2025. Suzetrigine has already been granted FDA Fast Track and Breakthrough Therapy designations for the treatment of moderate-to-severe acute pain.

“Today’s FDA filing acceptance for suzetrigine marks a critical milestone toward bringing this new, transformative non-opioid analgesic to the millions of patients suffering from moderate-to-severe acute pain each year in the U.S.,” said Nia Tatsis, Ph.D., Executive Vice President, Chief Regulatory and Quality Officer at Vertex. “The FDA’s granting of a priority review further reinforces the high unmet need in treating acute pain, and the filing brings us one step closer to our objective of filling the gap between medicines with good tolerability

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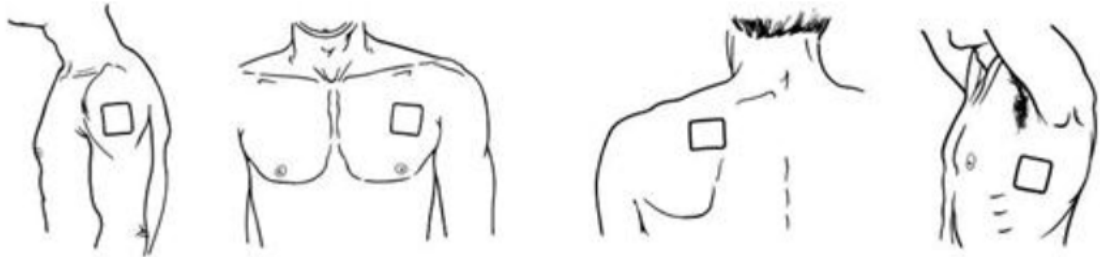
# PATCH PLACEMENT

## Before Applying BUTRANS:

- Do not use soap, alcohol, lotions, oils, or other products to remove any leftover adhesive from a patch because this may cause more BUTRANS to pass through the skin.
- Each patch is sealed in its own protective pouch. Do not remove a patch from the pouch until you are ready to use it.
- Do not use a patch if the seal on the protective pouch is broken or if the patch is cut, damaged or changed in any way.
- BUTRANS patches are available in different strengths and patch sizes. Make sure you have the right strength patch that has been prescribed for you.

## Where to apply BUTRANS:

- BUTRANS should be applied to the **upper outer arm, upper chest, upper back, or the side of the chest** (See Figure A). These 4 sites (located on both sides of the body) possible BUTRANS application sites.



If pt has excessive perspiration and/or the patch peels off early, you can have the pt place a transparent (Tagaderm) dressing over the patch for the entire week.

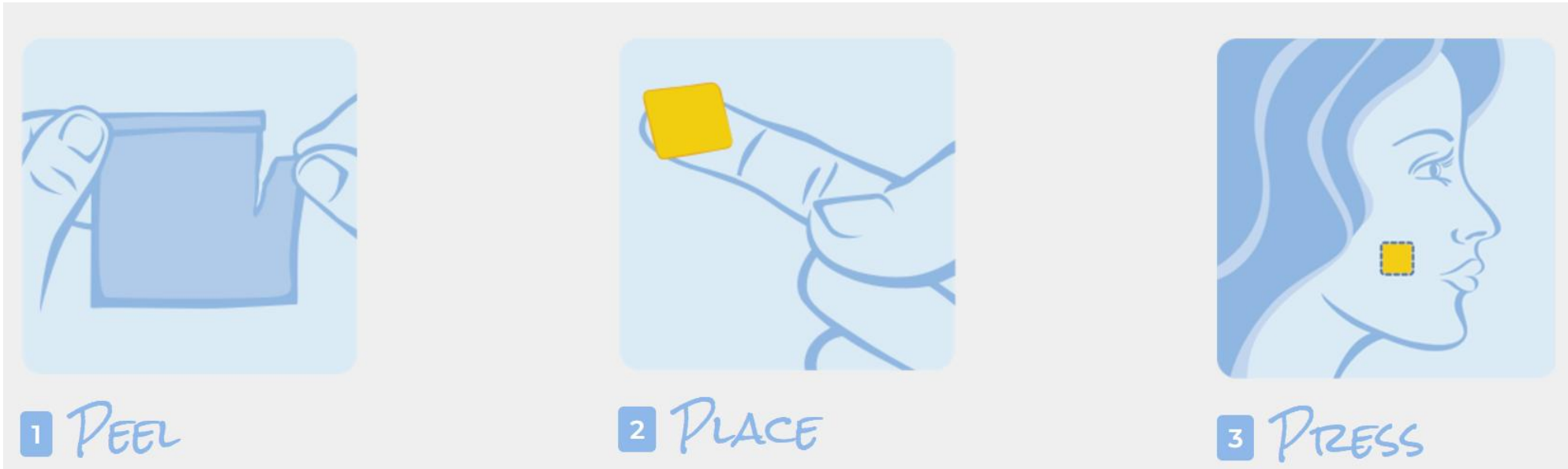
## Prior Auth language:

This is an URGENT prior auth request for Buprenorphine 5mcg qweekly patch – justification is for Chronic Pain (G89.4) in a pt who is too high risk for formulary full opioid agonist medications due to prior AUD or SUD history or active Cannabis Use Disorder. Transdermal buprenorphine is the safest option for this (geriatric) patient

Or pt is high risk due to COPD with chronic respiratory failure requiring oxygen or has a high risk of falls.



# FDA APPROVED BUCCAL BUPRENORPHINE - BELBUCA FOR PAIN



- With clean, dry fingers, **peel** open the foil package. Fold along the dotted line at the top of the package and tear at the perforation
- You can also use scissors to carefully cut along the dotted line

- Wet the inside of your cheek with your tongue or with water
- Carefully remove the BELBUCA film from the foil package and
- **Place** the film on your dry finger with the yellow side facing up

- **Press** the yellow side against the inside of your cheek. Hold it in place for 5 seconds, and then take your finger away
- Leave BELBUCA on the inside of your cheek until fully dissolved, usually within 30 minutes

# SUBLINGUAL BUPRENORPHINE/NALOXONE – SL FILM OR SL TABLETS

## HOW TO START:



Don't smoke for 30 minutes prior to taking bupe



Before taking bupe, take a sip of water



Put bupe under your tongue to left or right of the middle



Don't eat, drink, or talk until it has dissolved



- ☐ Start with a moist mouth, avoid acidic drinks (coffee or fruit juice)
- ☐ Avoid using nicotine products as this interferes with absorption
- ☐ Avoid speaking with the sublingual medication
- ☐ Keep dissolving medicine under tongue
- ☐ After medication is completely dissolved, leave in mouth an additional 5 min before swallowing or spitting remaining sputum
- ☐ Typically recommend avoiding eating, drinking, or smoking for 30 minutes after the medication dissolves.

# CLINICAL SCENARIO-2 INTRO

HPI: 73 year-old female with hypertension, COPD, depression, chronic low back pain with radiation down the L leg, cervicalgia, remote history of alcohol use disorder (but still occasionally drinks once a month on self report), former tobacco user, who presents to establish care for pain management. Pt was previously on methadone 10mg BID and oxycodone/APAP 10/325mg BID, but due to an abnormal heart rhythm, the methadone was stopped. Oxycodone dose increased to TID and pt started taking OTC Naprosyn for worsening pain. No other adjustment in regimen. Transferred her primary care due to being in severe pain. FHx: AUD, SUD

On exam, musculoskeletal exam reveals limited cervical and spine ROM, intact reflexes and strength, pt with depressed and tearful affect. Dental evaluation: edentulism.

PEG = 10/10/10

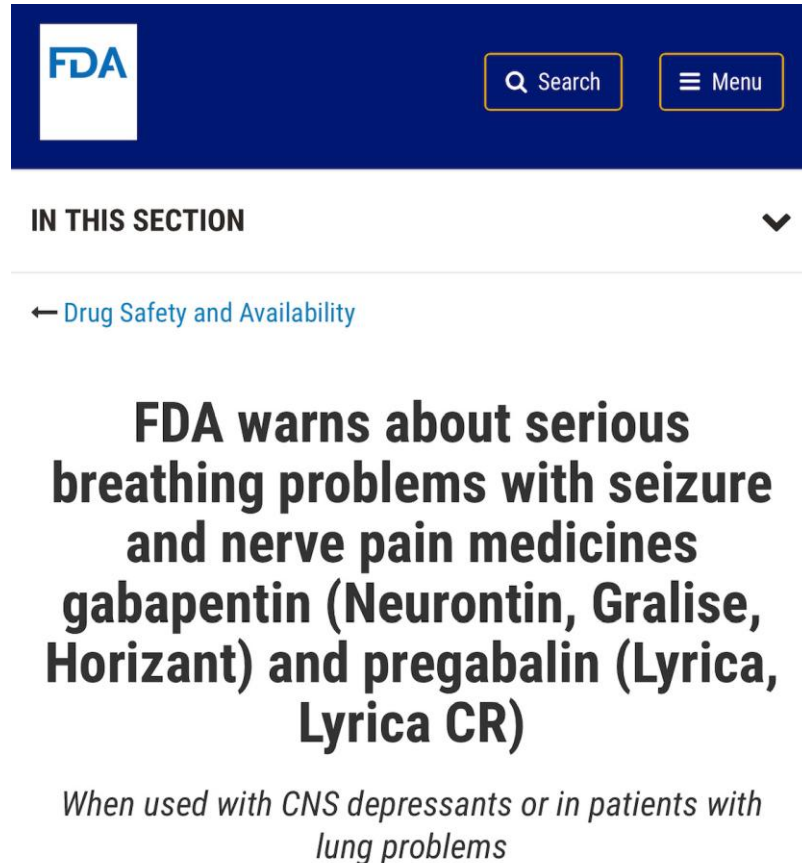
Urine toxicology: +OXY (GCMS consistent)

Outside records requested including imaging reports.



Codeine See Note 1	NEGATIVE ng/mL		<50 ng/mL
Hydrocodone See Note 1	NEGATIVE ng/mL		<50 ng/mL
Hydromorphone See Note 1	NEGATIVE ng/mL		<50 ng/mL
Morphine See Note 1	NEGATIVE ng/mL		<50 ng/mL
Norhydrocodone See Note 1	NEGATIVE ng/mL		<50 ng/mL
<b>Oxycodone</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;100 ng/mL</b>
<b>Noroxycodone</b> See Note 1	<b>7017 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
<b>Oxycodone</b> See Note 1	<b>4149 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
<b>Oxymorphone</b> See Note 1	<b>3370 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
Phencyclidine	NEGATIVE ng/mL		<25 ng/mL

# IS PREGABALIN SAFE?



The screenshot shows the top of the FDA website with a dark blue header containing the FDA logo, a search bar, and a menu button. Below the header, there is a section titled "IN THIS SECTION" with a dropdown arrow. A link labeled "← Drug Safety and Availability" is visible. The main content area features a bold headline: "FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)". Below the headline, a smaller line of text reads: "When used with CNS depressants or in patients with lung problems".

**FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)**

*When used with CNS depressants or in patients with lung problems*

12-19-2019 FDA Drug Safety Communication

## What safety concern is FDA announcing? ^

The U.S. Food and Drug Administration (FDA) is warning that serious breathing difficulties may occur in patients using gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system, and conditions such as chronic obstructive pulmonary disease (COPD) that reduce lung function. The elderly are also at higher risk.

# ARE NSAIDS OKAY?



IN THIS SECTION



← [Drug Safety and Availability](#)

**FDA Drug Safety  
Communication: FDA  
strengthens warning that non-  
aspirin nonsteroidal anti-  
inflammatory drugs (NSAIDs)  
can cause heart attacks or  
strokes**

❑ Not according to the FDA

❑ A large number of studies support the finding that NSAIDs cause an increased risk of serious cardiovascular thrombotic events, Estimates of increased RR range from 10% to 50%.

❑ Several observational studies found a significant cardiovascular risk within days to weeks of NSAID initiation. Some data also showed a higher risk with longer NSAID treatment.

❑ There are observational data indicating that the thrombotic cardiovascular risk from oral NSAID use is dose-related. There is also some evidence of this dose-response effect from clinical trials of celecoxib.

❑ **AVOID NSAIDS including Toradol IM in pts on ASA/Coumadin/NOAC therapy and with Chronic Kidney Disease!**



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# CLINICAL SCENARIO-2 SCREENINGS TO CONSIDER



PHQ-9: 17

GAD-7: 11

AUDIT-C: ??

ORT-R: ??



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# RECAP ON CLINICAL CASES

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# CLINICAL SCENARIO-1 REVIEW

50 y/o male with chronic pain - screenings reveal: PEG: 5/9/8 (avg. 7) on hydrocodone/APAP 10mg/325mg BID (illicit) + ibuprofen 600mg TID.

PHQ-9: 18

GAD-7: 14

AUDIT-C: was 8 (QUIT '24)

ORT-R: 5 (SUD/illicit Rx use/AUD, FHx: SUD, Depression)

- ☐ What are the best treatment options for him? Buprenorphine
- ☐ Does this patient meet criteria for OUD? Yes, likely mild OUD
- ☐ What additional treatment recommendations should be considered? To be discussed



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# CLINICAL SCENARIO-1

- Pain safety agreement signed & initiated – agrees to terms of bringing in pain medications to every visit and periodic UDS testing.
- Patient signed the MDHHS Opioid Consent
- EKG obtained: NSR, QTc 380ms
- Discontinuation of ibuprofen (or gradual reduction given her health risks)
- Consider physical therapy (but working)
- Referred to SUD therapist

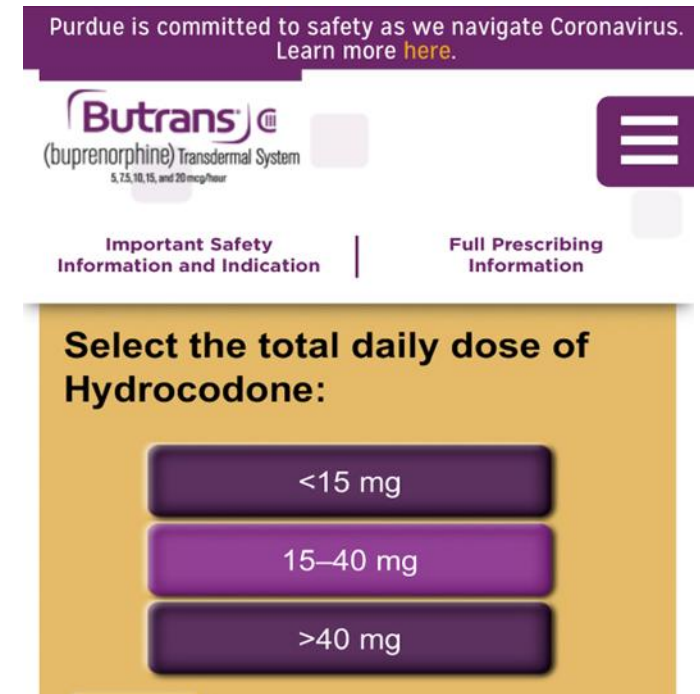
# CLINICAL SCENARIO-1 TRANSITION

❑ Rx: Buprenorphine 7.5mcg patch + Acetaminophen 500mg 1-2 tabs q6-8hr PRN

❑ Patient instructed start the patch 24 hours and to discontinue the use of hydrocodone & to use scheduled acetaminophen with lidocaine patches. Given short course of tizanidine to take PRN (denied having severe opioid withdrawal if he doesn't take hydrocodone).

❑ Side effects discussed including nausea and risk of rash with transdermal buprenorphine patch. Rotational pattern of patch reviewed.

❑ Patient returns in 2 weeks with improvement in pain to 3-4 and initiated whole body acupuncture treatments.



# CLINICAL SCENARIO-1 REVIEW

❑ Patient initially was misusing opioid therapy due to increased pain, but initially declined any interventions including PT.

❑Pt reports doing well on the buprenorphine 7.5mcg patch, but there was a delay in receiving his script through the pharmacy (schedule 3 formulations permit refills and concerns that the refill was not called in for pharmacy to order the patch) and he reported he had significant withdrawal and diarrhea. Admits to a lapse and took a couple of hydrocodone (illicit) a week ago when he did not have the patch in time. Also, admits he did 2 lines of cocaine and drank a couple of beers with his friend. He realizes it was not a good decision.

❑UDS checked +THC –bupe –opioids

❑Participating in SUD therapy.

❑What is advised if a patient declines continuation of buprenorphine for chronic pain due to lack of benefit?

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# CLINICAL SCENARIO-2 REVIEW

73 year-old female with hypertension, COPD, depression, chronic low back pain with radiation down the L leg, cervicalgia, remote history of alcohol use disorder (but still occasionally drinks once a month on self report), former tobacco user, who presents to establish care for pain management.

PHQ-9: 17

GAD-7: 11

AUDIT-C: 1

ORT-R: 4 (h/o AUD, dx of depression, FHx: AUD, SUD)

Pain agreement and opioid consent signed.

Medication adjustment is made as follows:

- Oxycodone/APAP increased to 4 times a day PRN pain
- Duloxetine 20mg daily prescribed
- Topical diclofenac prescribed - OTC NSAIDs discontinued



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# CLINICAL SCENARIO-2 REVIEW

Patient returns for close, ongoing follow up. Pain level at an 8/10 initially, but pt was unable to tolerate the duloxetine due to stomach upset and cramping, so she discontinued it. Clinically more depressed and encouraged to follow up with a therapist and consider an SSRI (escitalopram). Pt agreeable (but does not comply). At subsequent visit, pain level is back to 10/10 and pt in distress. UDS testing and PDMP checks are consistent. Clinical concern of opioid-induced hyperalgesia.

Reviewed MRI report from two years prior that confirms Cervical Spondylosis with broad-based disc osteophyte complexes. Severe right and moderate left foraminal narrowing C4-C5 and C6-C7. MRI also showed moderate to severe foraminal stenosis.

Repeat MRI imaging ordered and discussion for opioid conversion as pt has worsening pain despite dose adjustment two months prior. Conversion to long-acting opioid deemed too high risk with her COPD and age. Pt is concerned that even though it's been 4 months, she feels like she is still trying to cope with being off methadone. Declines injections, acupuncture and PT.

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## CLINICAL SCENARIO-2 CONVERSION TO BUCCAL BUPE

Within 2 weeks, patient returns with her adult daughter to discuss opioid conversion. Buprenorphine buccal films discussed and expedited prior authorization placed. Pt initiated on buccal buprenorphine 450 mcg BID – a taper off oxycodone/APAP is advised with treatment of withdrawal symptoms and pain using non-opioid analgesic agents, short course of tizanidine and gabapentin for the 24-48 hours after she tapers off the oxycodone. Family is available to support her through the conversion..

Patient transitions to buccal buprenorphine with notable improvement in pain with ultimate titration to 900mcg BID every 2-3 weeks.

Follow up MRI imaging confirms more moderate spine stenosis and compressive myelopathy of the spine. Patient's pain level is up to a 9/10 and asks if the buprenorphine can be increased to a higher dose beyond 900mcg BID. Patient referred to neurosurgery and again encouraged to make an appointment with a behavioral health therapist for integrative treatment options. Red flag symptoms discussed & pt denied.

# RECAP ON CLINICAL SCENARIO 2

- ❑ The question about the sudden discontinuation of methadone is worth exploring.
- ❑ Patient undergoes opioid conversion to buprenorphine buccal films and it is titrated, with addition of other modalities. The patient did not want to engage in injection treatments or PT, but she was receptive to hypnosis for pain management. The progression of her spine disease appropriately warrants a neurosurgical evaluation.
- ❑ Since her pain levels do not improve, offered transition to stronger buprenorphine formulation such as off label use of buprenorphine/naloxone for chronic pain, which she was agreeable to. Dose gradually increased to 8/2mg SL BID and pt hesitant to consider surgery.
- ❑ Since the Public Health Emergency ended – need to document opioid dependence (F 11.20, with caveat that pt does not have OUD, however insurance will not typically approve for off label pain management!

# ON / OFF LABEL TREATMENTS FOR PAIN

- ❑ Easiest to do if pt is already on buccal or transdermal buprenorphine
- ❑ Sometimes easier to get buprenorphine/naloxone covered than Belbuca, however buprenorphine/naloxone is MG dosing and Belbuca is MCG (microgram) so it's not UNCOMMON to have the patient cut the 2/0.5mg film in half and dissolve it sublingual 3-4 times a day for analgesic benefit.
- ❑ Annual renewal of any prior auth is required! Make sure the RN selects continuation of current treatment.
- ❑ Utilize the local Rexall Compound Pharmacy 810-344-6422 in Grand Blanc – Medicare Plan D does not cover compound topical agents, however, the cost is \$30-\$45 per month + \$5 courier fee for delivery anywhere in continental US:
  1. Ketoprofen 20% /Lidocaine 5% apply small amount TID – can also add gabapentin 5% (caution if already on a gabapentinoid but lowest systemic absorption)
  2. Prilocaine 2%/Lidocaine 5%/Gabapentin 5%/Ketoralac 2% - can also add amitryptiline
  3. Ketoprofen 10%/Ketoralac 2%/Piroxicam 2%/Cyclobenzaprine 5%/Gabapentin 5%

# DIALOGUE EXAMPLES

□“Many people struggle with taking opioids for chronic pain. What some people in your situation decide to do is consider a safer medication like a patch that works for a full week to deliver a steady stream of medication. I’m wondering if you have thought about that type of treatment since the pills seem to be less effective for you?”

□“What are some ways you think we could manage your pain while keeping you safe?”

□“If that’s not an option for you, perhaps you might be open to discussing other treatment options, such as buprenorphine.”



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# WHAT ABOUT CANNABIS?

CAUTION: Marijuana → current data shows worsening long-term outcomes especially with mood symptoms.

Consider avoiding full opioid agonists (ie, Hydrocodone/APAP) in patients using chronic marijuana use (falls, worsening mental health, suicidality, MVAs)

## Michigan Marijuana Legalization: Correlations Among Cannabis Use, Mental Health, and Other Factors

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### Abstract

**Introduction:** There are health implications with the statewide legalization of recreational marijuana that are still not fully understood and require further examination. This study evaluates the prevalence of marijuana use in patients being treated for a variety of conditions and whether correlations exist between marijuana use, mental health conditions, and concomitant use of psychotropic medications.

**Methods:** Data were collected from an electronic medical record (EMR) as part of a retrospective chart audit. A total of 500 charts were reviewed during a six-month timeframe from December 1, 2018 to May 31, 2019 with the start date approximating the timing of when marijuana became recreationally legalized in the State of Michigan.

**Results:** This study demonstrated a point prevalence of 15.8% since 79 of the 500 charts reviewed had marijuana use documented. Additionally, marijuana users were more likely to have a history of cocaine use, schizophrenia, antipsychotic use, and tobacco use.

**Conclusion:** Trends identified in this study provide a comparison point for the local prevalence of marijuana use immediately post state-wide legalization, with a projected increasing trend due to the removal of legal barriers.

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### Key Points










**Question** Does acupuncture alleviate pain and improve function in patients with chronic sciatica from herniated disk?

**Findings** This multicenter randomized clinical trial found a statistically significant difference in the mean decrease in leg pain using the visual analog scale, from baseline to week 4 (30.8 mm with acupuncture vs 14.9 mm with sham acupuncture). The findings for function using the Oswestry Disability Index were similar (13.0 vs 4.9 points).

**Meaning** Acupuncture alleviates pain and improves function among patients with chronic sciatica from herniated disk and should be considered as a potential treatment option.

- ❑ If there is Mental Health co-morbidity, connect patients with a Behavioral Health Therapist as a part of their pain agreement, and/or a psychiatrist.
- ❑ Encourage gradual tapering of marijuana (if they test +THC) due to risks, including Cannabinoid Hyperemesis Syndrome. Do not abruptly have patients stop cannabis! It causes withdrawal with abrupt cessation.
- ❑ Do not assume a patient's pain management and concomitant benzodiazepine prescribing – it is a very high-risk combination and pts should be seeing a psychiatrist.
- ❑ Consider doing pill/medication counts. If concerns over diversion, schedule an RN visit for a POC UDS and medication count between scripts.
- ❑ Consider integrative health options including TENS units, mindfulness-based stress meditation, including acupuncture (Medicare Plan B covers up to 20 treatments per year for chronic Low Back Pain).
- ❑ Provide the MDHHS MICAL Peer Warmline: 1-888-733-7753 hours 10am to 2am / 7 days a week including holidays. Up to two 20 min calls per day. No time limit.

## FALSE POSITIVES

Device Strip	Drug or Drug Class	Abbrev.	Drugs Targeted by an Instant Read Test	Substances Known to Cause a False Postive Test Result
	Amphetamine	AMP	Amphetamine (i.e. Adderall®) Note: Amphetamine is a metabolic product of Benzphetamine, Selegiline and Famprofazone.	Phenylpropanolamine, Ephedrine, Pseudoephedrine, Ranitidine, Phentermine, Brompheniramine, Bupropion, Trazodone, Chlorpromazine, Promethazine, Dimethylamylamine. (Vicks® Nasal Inhaler metabolizes to Amphetamine in the body.)
	Barbiturates	BAR	Butalbital, Phenobarbital, Secobarbital, Amobarbital and other Barbiturates	Ibuprofen, Naproxen
	Benzodiazepines	BZO	Oxazepam, Nordiazepam, Temazepam, Alprazolam and other Benzodiazepines to varying degrees	Oxaprozin, Sertraline
	Cocaine	COC	Cocaine	Unknown/Infrequent
	Methadone	MTD	Methadone	Verapamil, Quetiapine, Diphenhydramine, Doxylamine, Chlorpromazine
	Methamphetamine	MET	Methamphetamine Note: Methamphetamine is a metabolic product of Benzphetamine, Selegiline and Famprofazone.	Adderall®, Phenylpropanolamine, Ephedrine, Pseudoephedrine, Ranitidine, Phentermine, Brompheniramine, Bupropion, Trazodone, Chlorpromazine, Promethazine. (Vicks® Nasal Inhaler (l-isomer), illicit (d-isomer) metabolizes to Amphetamine in the body.)
	Methylenedioxy-methamphetamine	MDMA	Methylenedioxymethamphetamine	Phenylpropanolamine, Ephedrine, Pseudoephedrine, Ranitidine, Phentermine
	Opiates	OPI	Codeine, Morphine, Hydrocodone, Hydromorphone	Oxycodone (at high concentrations) and poppy seeds (which contain morphine), certain quinolones
	Oxycodone	OXY	Oxycodone, Oxymorphone	Codeine, Morphine, Hydrocodone, Hydromorphone
	Phencyclidine	PCP	Phencyclidine	Venlafaxine, Dextromethorphan, Diphenhydramine, Ibuprofen, Tramadol
	THC (Marijuana)	THC	Marijuana, Marinol, Dronabinol	Prilosec®, Protonix®, Efavirenz, Nsaids
	Tricyclic Antidepressants	TCA	Amitriptyline, Nortriptyline, Imipramine, Desipramine, Doxepin and other Tricyclics to varying degrees	Cyclobenzaprine, Carbamazepine, Diphenhydramine



# “THE OPPOSITE OF ADDICTION IS NOT SOBRIETY...”

**...it's Human Connection.**

<https://www.youtube.com/watch?v=PY9DcIMGxMs&t=2s>

If a use disorder manifests, then treat the person suffering with the disease; avoid the stigma of treating addiction as if it is a personality flaw or a moral failing.





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THANK YOU.

QUESTIONS?

CONTENT IS FOR EDUCATIONAL  
PURPOSES ONLY. PERMISSION IS  
REQUIRED IN ADVANCE TO USE  
ANY OF THESE SLIDES.

JM.PERZHINSKY@CMICH.EDU



70 year Female not prescribed recent hydrocodone/APAP, ORT-R: 3 (denied taking any non prescribed hydrocodone) - initial GCMS:

1

**DRUG MONITORING, PANEL 6 WITH CONFIRMATION, URINE**

Alcohol Metabolites	NEGATIVE ng/mL		<500 ng/mL
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Barbiturates	NEGATIVE ng/mL		<300 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
Marijuana Metabolite	NEGATIVE ng/mL		<20 ng/mL
Methadone Metabolite	NEGATIVE ng/mL		<100 ng/mL
<b>Opiates</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;100 ng/mL</b>
Codeine	NEGATIVE ng/mL		<50 ng/mL
<b>Hydrocodone</b>	<b>1952 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
<b>Hydromorphone</b>	<b>241 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
Morphine	NEGATIVE ng/mL		<50 ng/mL
<b>Norhydrocodone</b>	<b>1926 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>

Same 70 year old F placed on Buprenorphine patch and admitted to taking hydrocodone/APAP from dentist who prescribed 12 prescribed 3 weeks prior – POC UDS +opioids, - bupe:

2

**DRUG MONITORING, PANEL 8 WITH CONFIRMATION, URINE**

Alcohol Metabolites	NEGATIVE ng/mL		<500 ng/mL
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
<b>Buprenorphine</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;5 ng/mL</b>
<b>Buprenorphine</b>	<b>5 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
<b>Norbuprenorphine</b>	<b>16 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
Naloxone	NEGATIVE ng/mL		<2 ng/mL
Buprenorphine Comments	See Buprenorphine Notes, LDT Notes		
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
Marijuana Metabolite	NEGATIVE ng/mL		<20 ng/mL
MDMA	NEGATIVE ng/mL		<500 ng/mL
<b>Opiates</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;100 ng/mL</b>
Codeine	NEGATIVE ng/mL		<50 ng/mL
<b>Hydrocodone</b>	<b>&gt;10000 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
<b>Hydromorphone</b>	<b>1093 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
Morphine	NEGATIVE ng/mL		<50 ng/mL
<b>Norhydrocodone</b>	<b>&gt;10000 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>

Same 70 year old F - Pt then converted to and stabilized on buprenorphine/naloxone 2/0.5mg TID - follow up UDS only showed Bup 4 weeks after this GCMS):

3

**DRUG MONITORING, PANEL 8 WITH CONFIRMATION, URINE**

Alcohol Metabolites	NEGATIVE ng/mL		<500 ng/mL
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
<b>Buprenorphine</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;5 ng/mL</b>
<b>Buprenorphine</b>	<b>35 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
<b>Norbuprenorphine</b>	<b>280 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
<b>Naloxone</b>	<b>141 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
Buprenorphine Comments	See Buprenorphine Notes, LDT Notes		
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
Marijuana Metabolite	NEGATIVE ng/mL		<20 ng/mL
MDMA	NEGATIVE ng/mL		<500 ng/mL
<b>Opiates</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;100 ng/mL</b>
Codeine	NEGATIVE ng/mL		<50 ng/mL
<b>Hydrocodone</b>	<b>94 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
<b>Hydromorphone</b>	<b>121 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
Morphine	NEGATIVE ng/mL		<50 ng/mL
<b>Norhydrocodone</b>	<b>137 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>

## CASE EXAMPLES

62 year old Male on Transdermal Buprenorphine for 3 years. Current dose: 20mcg qweekly. Admits to daily, chronic cannabis use.

### DRUG MONITORING, PANEL 8 WITH CONFIRMATION, URINE

Alcohol Metabolites	NEGATIVE CONFIRMED ng/mL		<500 ng/mL
Ethyl Glucuronide (ETG)	NEGATIVE ng/mL		<500 ng/mL
Ethyl Sulfate (ETS)	NEGATIVE ng/mL		<100 ng/mL
Alcohol Metab Comments See LDT Notes			
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
<b>Buprenorphine</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;5 ng/mL</b>
<b>Buprenorphine</b>	<b>49 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
<b>Norbuprenorphine</b>	<b>26 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
Naloxone	NEGATIVE ng/mL		<2 ng/mL
Buprenorphine Comments See Buprenorphine Notes, LDT Notes			
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
<b>Marijuana Metabolite</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;20 ng/mL</b>
<b>Marijuana Metabolite</b>	<b>&gt;5000 ng/mL</b>	<b>H</b>	<b>&lt;5 ng/mL</b>
Marijuana Comments See Marijuana Notes, LDT Notes			



59 year old Female with chronic pain using clonazepam and using THC, on buprenorphine patch 10mcg qweekly. POC UDS +BZP, +THC, -BUPE

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**DRUG MONITORING, PANEL 8 WITH CONFIRMATION, URINE**

Alcohol Metabolites	NEGATIVE ng/mL		<500 ng/mL
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
<b>Benzodiazepines</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;100 ng/mL</b>
Alphahydroxyalprazolam	NEGATIVE ng/mL		<25 ng/mL
Alphahydroxymidazolam	NEGATIVE ng/mL		<50 ng/mL
Alphahydroxytriazolam	NEGATIVE ng/mL		<50 ng/mL
<b>Aminodiazepam</b>	<b>33 ng/mL</b>	<b>H</b>	<b>&lt;25 ng/mL</b>
Hydroxyethylflurazepam	NEGATIVE ng/mL		<50 ng/mL
Lorazepam	NEGATIVE ng/mL		<50 ng/mL
Nordiazepam	NEGATIVE ng/mL		<50 ng/mL
Oxazepam	NEGATIVE ng/mL		<50 ng/mL
Temazepam	NEGATIVE ng/mL		<50 ng/mL
Benzodiazepines Comments			
See Benzodiazepines Notes, LDT Notes			
Buprenorphine	NEGATIVE ng/mL		<5 ng/mL
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
<b>Marijuana Metabolite</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;20 ng/mL</b>
<b>Marijuana Metabolite</b>	<b>145 ng/mL</b>	<b>H</b>	<b>&lt;5 ng/mL</b>



76 year old Female with OUD, COPD on stable buprenorphine/naloxone 8/2mg SL TID:

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**DRUG MONITORING, PANEL 8 WITH CONFIRMATION, URINE**

Alcohol Metabolites	NEGATIVE ng/mL		<500 ng/mL
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
<b>Buprenorphine</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;5 ng/mL</b>
<b>Buprenorphine</b>	<b>677 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
<b>Norbuprenorphine</b>	<b>1508 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
<b>Naloxone</b>	<b>226 ng/mL</b>	<b>H</b>	<b>&lt;2 ng/mL</b>
Buprenorphine Comments	See Buprenorphine Notes, LDT Notes		
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
Marijuana Metabolite	NEGATIVE ng/mL		<20 ng/mL
MDMA	NEGATIVE ng/mL		<500 ng/mL
Opiates	NEGATIVE ng/mL		<100 ng/mL
Oxycodone	NEGATIVE ng/mL		<100 ng/mL
Creatinine	46.6 mg/dL		> or = 20.0 mg/dL
pH	7.1		4.5-9.0
Oxidant	NEGATIVE mcg/mL		<200 mcg/mL

68 year old Male seen for initial visit for pain mgmt, ORT-R: 2-3 (pt would not respond to and evaded Family Hx questions re: SUD), admitted to prior cocaine use, but not for years – panel 6 GCMS on initial visit showed:

**DRUG MONITORING, PANEL 6 WITH CONFIRMATION, URINE**

Alcohol Metabolites	NEGATIVE ng/mL		<500 ng/mL
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Barbiturates	NEGATIVE ng/mL		<300 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
<b>Cocaine Metabolite</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;150 ng/mL</b>
<b>Benzoyllecgonine</b>	<b>261 ng/mL</b>	<b>H</b>	<b>&lt;100 ng/mL</b>
Cocaine Comments			
See Cocaine Notes, LDT Notes			
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
Marijuana Metabolite	NEGATIVE ng/mL		<20 ng/mL
Methadone Metabolite	NEGATIVE ng/mL		<100 ng/mL
Opiates	NEGATIVE ng/mL		<100 ng/mL
Oxycodone	NEGATIVE ng/mL		<100 ng/mL
Phencyclidine	NEGATIVE ng/mL		<25 ng/mL
Creatinine	89.5 mg/dL		> or = 20.0 mg/dL
pH	4.8		4.5-9.0
Oxidant	NEGATIVE mcg/mL		<200 mcg/mL

68 Year old Male with chronic pain, self report of drinking 2 beers the day before, denies any opioid use, currently awaiting an appt with a therapist:

**Date of Specimen:** 10/07/2024 09:56:00    **Date Received:** 10/08/2024 04:33:00    **Specimen Source:**  
**Date Reported:** 10/09/2024 18:07:00    **Physician:** PERZHINSKY, JULIETTE    **Information:**

Test Name	Result	Flags	Reference Rang
<b>DRUG MONITORING, PANEL 6 WITH CONFIRMATION, URINE</b>			
<b>Alcohol Metabolites</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;500 ng/mL</b>
<b>Ethyl Glucuronide (ETG)</b>	<b>&gt;100000 ng/mL</b>	<b>H</b>	<b>&lt;500 ng/mL</b>
<b>Ethyl Sulfate (ETS)</b>	<b>&gt;100000 ng/mL</b>	<b>H</b>	<b>&lt;100 ng/mL</b>
Alcohol Metab Comments See Alcohol Metab Notes, LDT Notes			
Amphetamines	NEGATIVE ng/mL		<500 ng/mL
Barbiturates	NEGATIVE ng/mL		<300 ng/mL
Benzodiazepines	NEGATIVE ng/mL		<100 ng/mL
Cocaine Metabolite	NEGATIVE ng/mL		<150 ng/mL
6 Acetylmorphine	NEGATIVE ng/mL		<10 ng/mL
Marijuana Metabolite	NEGATIVE ng/mL		<20 ng/mL
Methadone Metabolite	NEGATIVE ng/mL		<100 ng/mL
<b>Opiates</b>	<b>POSITIVE ng/mL</b>	<b>A</b>	<b>&lt;100 ng/mL</b>
Codeine	NEGATIVE ng/mL		<50 ng/mL
Hydrocodone	NEGATIVE ng/mL		<50 ng/mL
Hydromorphone	NEGATIVE ng/mL		<50 ng/mL
<b>Morphine</b>	<b>201 ng/mL</b>	<b>H</b>	<b>&lt;50 ng/mL</b>
Norhydrocodone	NEGATIVE ng/mL		<50 ng/mL

1

Same 68 Year old Male with chronic pain. A follow up serum PEth level is substantially elevated despite pt self report of consuming only 2-3 beers a week:

o Drug Monitoring, Phosphatidylethanol (PEth), Blood (80321) - V49.89/Z78.9 - 11/04/2024 - Hold lab results until reviewed :No

2

DRUG MONITOR, PHOSPHATIDYLETHANOL, B			
PEth 16:0/18:1 (POPEth)	>400 ng/mL	H	<20 ng/mL
PEth 16:0/18:2 (PLPEth)	>400 ng/mL	H	<20 ng/mL
PEth Comments			
See LDT Notes			



**DRUG MONITORING TEMPLATE**

labgenerated    Notes and Comments

This drug testing is for medical treatment only. Analysis was performed as non-forensic testing and these results should be used only by healthcare providers to render diagnosis or treatment, or to monitor progress of medical conditions.

PEth is a direct biomarker of alcohol consumption because it's only produced when alcohol reacts with phosphatidylcholine, a phospholipid in cell membranes.

**PEth <20ng/mL:**  
Abstinence or irregular low alcohol consumption in the approximate month prior to the sample collection.

**PEth between 20 – 200ng/mL:**  
Consistent with alcohol consumption, but not at an excessive level, in the approximate month prior to the sample collection.

**PEth >200 ng/mL:**  
Excessive alcohol consumption in the approximate month prior to the sample collection.