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Health

# Buprenorphine for chronic pain

## Starting, transitioning, and perioperative pain control

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**Montana Academy of Family Physicians Annual Meeting, Chico Hot Springs, Pray, MT**
**June 20, 2024**

# Disclosures

- Buprenorphine SL tablets and Buprenorphine/naloxone films are not FDA approved for treatment of chronic pain

# Objectives

1. Understand the current scope of the opioid overdose epidemic in Montana and the United States
2. Become familiar with national guidelines for treating non-cancer chronic pain
3. Understand the pharmacodynamics, pharmacokinetics, side effect profile, and DEA designation of available buprenorphine products
4. Understand the benefits of choosing buprenorphine products over full agonist opioid therapy for treatment of non-cancer chronic pain
5. Review perioperative considerations in patients being prescribed buprenorphine products

# A Rural Montana Case

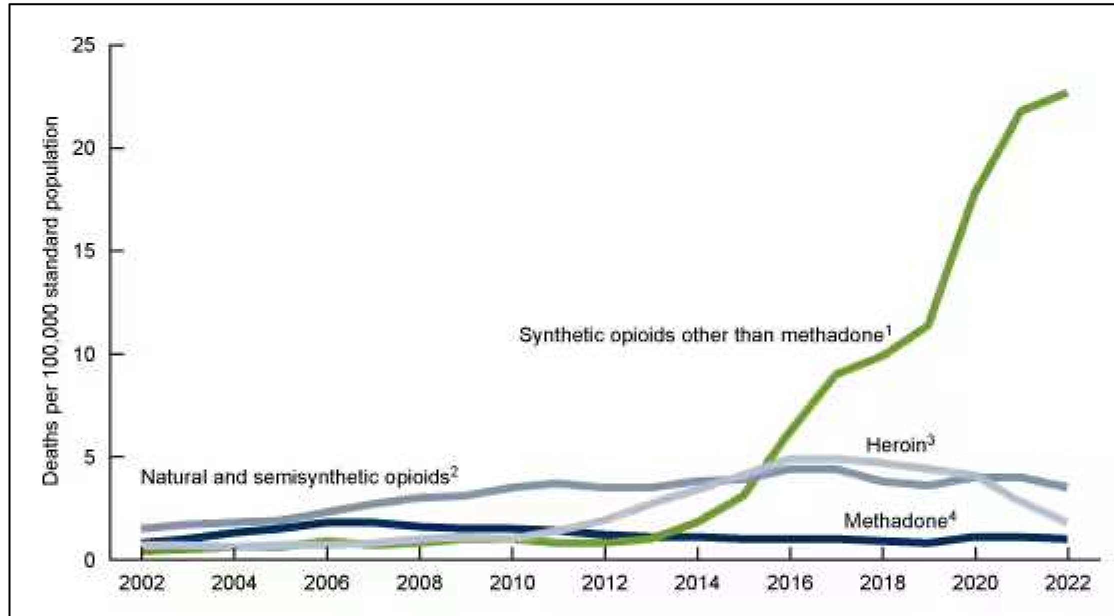
CC: 67yo M, Follow up chronic neck pain, s/p remote discectomy

HPI: Someone "maybe a social circle friend" took 3 weeks of his opioid medication from his house, in his bathroom, from his 4 week pill box. They missed one day's worth. Doesn't normally lock his doors "I'm well armed". Didn't make a police report. Has been out of opioids for 2 weeks now. He is frustrated and "weirded out". Knows he is not able to pick up new Rx's until 3 days from now. Wants to consider weekly prescriptions so that he doesn't have so much laying around. Has a lockbox and hadn't considered using that before because he lives alone.

Godchild sent $15K of his money to someone she met online, so he is also very stressed about that

# The opioid epidemic

Age-adjusted rate of drug overdose deaths involving opioids, by type of opioid: United States, 2002–2022




CDC, 3/2024

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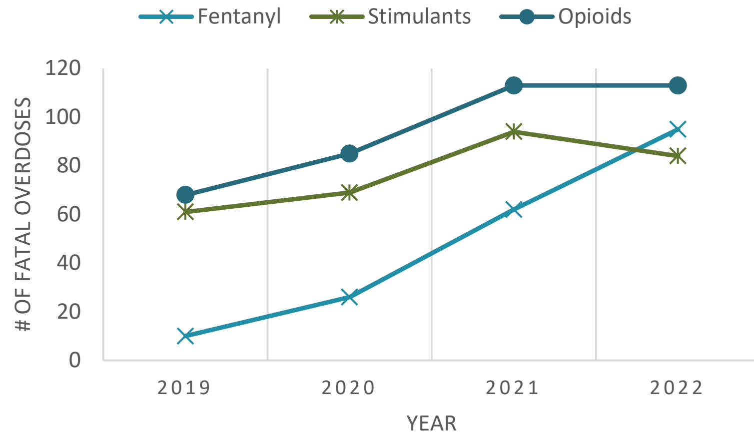
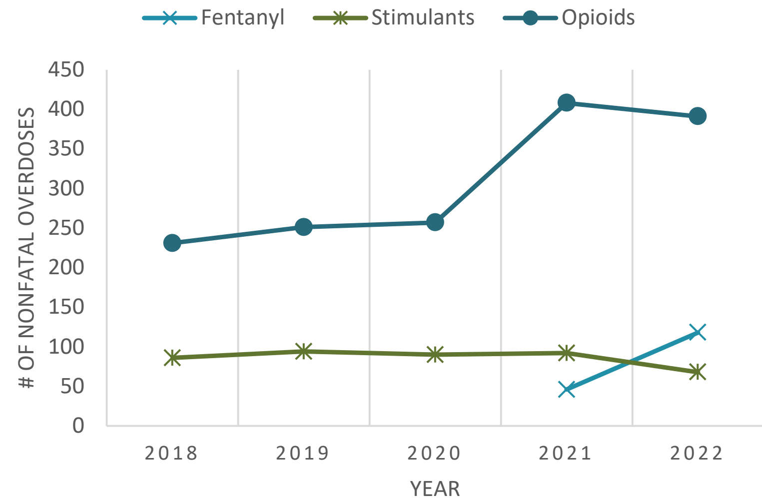
# The opioid epidemic




MT DPHHS, EMSTS data set

# The opioid epidemic

- Stimulants involved in ODs were methamphetamine
- Benzodiazepines involved in fatal OD in 2024 when combined with alcohol or fentanyl
- Alcohol involved in 1/3 of overdoses

# The opioid epidemic

## Overdoses in Yellowstone County, Montana, January 2023 - April 2024

# of overdoses

| | Jan'23 | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan'24 | Feb | Mar | Apr |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Overdoses | 21 | 16 | 17 | 19 | 18 | 19 | 20 | 18 | 3 | 19 | 15 | 9 | 14 | 12 | 18 | 16 |
| Fatal Overdoses | 4 | 2 | 3 | 2 | 2 | 6 | 3 | 2 | 0 | 12 | 2 | 1 | 1 | 0 | 0 | 2 |
| Naloxone Administered | 8 | 9 | 4 | 8 | 10 | 6 | 8 | 6 | 2 | 2 | 7 | 5 | 5 | 7 | 7 | 6 |

Month

Total Overdoses   Fatal Overdoses   Naloxone Administered

# The opioid epidemic

- Naloxone used in 37-38% of overdoses in MT and Yellowstone Co
- Naloxone was used in only 19-26% of fatal overdoses

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# Opioids for pain

OPAL Trial – Lancet, June 26, 2023

- Randomized placebo-controlled trial, n=347
- Adults with acute/subacute neck or low back pain (<12 wks)
- Guideline care + oxycodone or placebo x 6 wks
- Outcomes
  - Mean score on Brief Pain Inventory borderline higher in opioid group (Mean diff 0.53, 95% CI 0.00-1.07)
  - More AEs in opioid group

# Chronic pain in primary care

## Billings Pain Center patient speaks on closure in 2024

Connor McEvoy KULR 8 Reporter   Oct 24, 2023

"…[P]atients living in Eastern Montana are concerned about access to the medical care the center offers. "I'm going to lose my access to good quality healthcare," said…a patient at the center.

[The patient] lives in Forsyth, and said the access to the care he needs for his health related problems is limited.

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# Chronic pain in primary care

Responding to Pain Clinic Closures

A GUIDE FOR STATE HEALTH DEPARTMENTS

JUNE 2020

"Identify and connect with other stakeholders who may be involved in or affected by a clinic closure, for example:

- Emergency departments
- Primary and ambulatory care clinics
- State medical review board
- Health systems and quality assurance"

https://www.astho.org/globalassets/pdf/pain-clinic-closures-guide.pdf

# Chronic pain in primary care

- Assess the number of pain clinics in the state and their capacity to accept new patients
- If possible, verify the number of MAT-waivered providers and assess their experience with MAT
- Review location of waivered prescribers; if there is a deficit, consider models of telehealth across the state

https://www.astho.org/globalassets/pdf/pain-clinic-closures-guide.pdf

# Chronic pain in primary care

- Work with the clinic or other authorized PDMP users to estimate the critical period during which most patients will be out of their medications
- Make sure there is a clear line of command and channels of communication

https://www.astho.org/globalassets/pdf/pain-clinic-closures-guide.pdf

# Chronic pain in primary care

- DATA-Waiver Program eliminated in CAA of 2023
- These transitions can happen inter-office or inter-office!
  - E.g. “legacy patients” who you may identify as having risks for ongoing full opioid agonist therapy

# Chronic Pain Guidelines

## CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

*Recommendations and Reports* / November 4, 2022 / 71(3);1–95

- Chronic pain often co-occurs with behavioral health conditions, including mental and substance use disorders
- Patients with chronic pain also are at increased risk for suicidal ideation and behaviors
- Recommendations should not be applied as inflexible standards of care across patient populations

# Chronic Pain Guidelines

- Rx opioids for acute pain at lowest effective dose, for no longer than the expected duration of pain severe enough to require opioids
- Maximize use of nonopioid pharm, nonpharm therapies
- Consider concurrent medical conditions
  - OSA, pregnancy, renal/hepatic insufficiency, mental health conditions, substance use disorders, concurrent benzo use
- Offer naloxone, particularly if patient or household member has risk factors for overdose, and for pts ≥50 MME/day
- Check the PDMP

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# VA DoD 2023 Guidelines

## Rethinking the Appropriateness of Opioids

The U.S. is undergoing a cultural transformation in the way pain is viewed and treated. Experts agree that opioids should not be considered first line or routine therapy for chronic pain, outside of active cancer, palliative, and end-of-life care. (p. 7)[1]

We recommend **against** the initiation of opioid therapy for the management of chronic non-cancer pain (for non-opioid treatments for chronic pain, see the VA/DOD CPGs for Low Back Pain,[2] Headache,[3] and Hip and Knee Osteoarthritis[4]). (p. 35)[1]

For patients receiving daily opioids for the treatment of chronic pain, **we suggest** the use of buprenorphine instead of full agonist opioids due to lower risk of over-dose and misuse. (p. 43)[1]

https://www.healthquality.va.gov/guidelines/Pain/cot/Rethinking_Opioids_CST_Final02092_508.pdf

# Messaging to Patients

## Did You Know?

- Healthcare providers used to think that opioids alone were safe and effective in treating chronic pain. Now we know this isn't true.
- New information has shown that chronic pain treatment requires a multimodal approach. This type of approach includes various treatment options and disciplines working together to help a patient with their pain condition. It also includes self-management options.
- Long-term opioid use can lead to multiple problems including loss of pain-relieving effects, increased pain, accidental death, opioid use disorder or addiction, and problems with sleep, mood, hormones, and the immune system.
- It is now understood that the best treatments for chronic pain are not opioids.
- When considering the benefits and harms of various treatments, non-medication treatments may provide the most benefit with the least risk of harm.

https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOpioidsCPGPatientSummary.pdf

# Buprenorphine (DEA Schedule III)

- **Partial mu agonist**, kappa (& delta) antagonist, also binds nociceptin opioid peptide receptor
  - Strong mu binding affinity, slow dissociation, high lipophilicity
- “Massive” first-pass hepatic metabolism when taken orally
- Measurable in serum 10-20 min, peak ~3 hrs, ½ life 37 hrs
- CYP3A4 metabolism
- Active metabolite – norbuprenorphine
- Possibility of QT prolongation

# Who might benefit?

- *Pain severe enough to require around-the-clock, long-term opioid treatment
- *Risk factors for overdose or other accidental injury
  - Pulmonary disease
  - Fall risk
  - Polypharmacy/concurrent sedative use
  - Substance Use Disorder
- Patients who might like idea of less frequent dosing, less constipation

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# Case

- 70 yo F, chronic severe shoulder OA, not surgical candidate due to medical comorbidities, severe lumbar facet arthropathy
- COPD, Asthma, OSA, Osteoporosis, CKD3a, BMI 45.6
- Requires walker for most ambulation, can walk 30 feet without walker, then requires rest due to dyspnea
- Constipation
- Lamictal, Latuda, Clonazepam once a week

- Fentanyl 25mcg/h patch q72h, hydromorphone 2mg TID

# At RiverStone Health Clinic

All patients

- SBIRT screening at entry to care and yearly
- PHQ9 screening at entry and every 90 days
- PDMP embedded in EMR

# At RiverStone Health Clinic

<u>Structured Team Based Approach to Chronic Pain</u>

- Interdisciplinary, patient centered, individualized approach
- Focus on multimodal treatment
- Includes pain assessment metrics, goals, screening tools
- Address behavioral health
- Aim is for improved overall function

# At RiverStone Health Clinic

3 visit process

- Chronic pain is a chronic disease – eval takes >20 min
- Visit 1 – education/expectations, UDS, PEG, ORT or other opioid misuse screening tool, PHQ-9, PDMP, brief HPI to identify pain generator and need for ROI, *other risk factors for overdose
- Visit 2 – review records, focused exam
- Visit 3 – establish diagnosis, complete a care plan including SMART goals, ideally warm handoff to BH team member

Visit 2&3 – same experienced non-APP provider

# Morphine Equivalent Dosing

| Opioid (oral or transdermal): | mg per day:* | |
|---|---|---|
| Buprenorphine transdermal (in mcg/hr) | | 0 |
| Codeine | | 0 |
| Fentanyl transdermal (in mcg/hr) | 25 | 60 |
| Hydrocodone | | 0 |
| Hydromorphone | 6 | 30 |
| Methadone† | | 0 |
| Morphine | | 0 |
| Oxycodone | | 0 |
| Oxymorphone | | 0 |
| Tapentadol | | 0 |
| Tramadol | | 0 |
| | **Total** | **90** |

https://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator

# BUPRENORPHINE FORMULATIONS FOR CHRONIC PAIN MANAGEMENT IN PATIENTS WITH OPIOID USE DISORDER OR ON LONG-TERM OPIOID THERAPY WITH PHYSIOLOGIC TOLERANCE

**Buprenorphine Inj, Buprenorphine TDS, Buprenorphine SL Film, Buprenorphine/Naloxone SL tabs**

**Recommendations for Use**

**Rev. April 2023**

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives; National Mental Health Office – Substance Use Disorders; National Pain Management Strategy Coordinating Committee

# Conversion Methods

- Taper MED's to 30 by 10-12%/week; can go slower
- Convert to buprenorphine, patients should be in mild withdrawal (12-24h since last dose)
- Bernese method – conversion over 5-14 days for those at higher MEDs

Shared decision making, provider comfort, supportive services will affect choices

# Tapering Opioids

- Ensure screening/treatment offered for conditions that can complicate pain management before initiating
  - Optimize mental health disease control
  - SBIRT
  - Kidney/CV or liver disease
  - Fall risk (e.g. CDC STEADI)

**Opioid Taper Decision Tool (VA Clinician's Guide 2016)**

# Withdrawal Management

- Autonomic symptoms
  - Clonidine 0.05-0.2 mg orally q6 to 8 hours (I give 0.1mg ½-1 tab up to 3x/d, #42)
- Anxiety, dysphoria, lacrimation, rhinorrhea
  - Hydroxyzine 25 to 50 mg three times a day as needed
  - Diphenhydramine 25 mg q6 hours as needed
- Myalgias
  - NSAIDs, Acetaminophen
- Sleep disturbance
  - Trazodone 25 to 100 mg orally at bedtime, Hydroxyzine
- Nausea
  - Ondansetron 4mg Q6 hours as needed
- Diarrhea
  - Loperamide not to exceed 16mg daily, Bismuth subsalicylate

# Buprenorphine Transdermal System

- “Butrans” weekly patch
  - 5mcg/h patch starting dose if on <30 MEDs
  - 10mcg/h patch starting dose in on 30-80 MED’s
  - >80 MED’s – consider another formulation

Ok to supplement with short acting opioids until analgesic efficacy is attained (72h)

Consider scheduling NSAIDs if not contraindicated

# Buprenorphine Transdermal System

- Comes in a box of 4 patches
- Rotate site for each patch of a box, then repeat
- Titrate up as needed
  - 10, 15, Max 20mcg/h

# Buprenorphine Buccal Film

- BID medication
- Less than 30 MED – 75mcg q 12 hrs
- 30-90 MED's - 150mcg q 12 hrs
- 90-160 MED's – 300mcg q 12 hrs
- >160 consider buprenorphine SL tablets

# Case

**Chief Complaint**
Patient presents with

- Neck Pain

  *Neck and back pain follow-up*

**Subjective:**

Patient comes in today for routine pain management follow-up. He has a long history of chronic cervical pain. He has had multiple previous cervical spine surgeries. Recent EMG showed carpal tunnel on the right as well as some ulnar neuropathy. He had evidence of bilateral chronic C5/6/7 radiculopathy without evidence of acute denervation. He is working with neurosurgery about this issue. Over the last couple of months he has been weaning down on his oxycodone from 30 mg up to 7 tablets in a 24-hour period down to 20 mg up to 7 tablets in 24-hour period. He is found this reduction has greatly worsened his quality life and functional status. He does not feel he can go much lower than this. In the past he has had both alcohol and THC in urine samples but denies the use of either today.

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# Buprenorphine SL & Bup/naloxone

- Stop opioids the day prior – patient should be in mild withdrawal
- BID or TID dosing better for pain
- 2-4mg/day in divided doses is adequate for most
  - Pain doses/day much lower than mg needed to treat OUD
- Patients with OUD and chronic pain may need more or less depending on their recovery

# Bernese Method – Bup SL

Subutex 2mg tablets - 19 tablets total for 7 days
Day 1: ½ tablet(1mg) in the morning. Continue old meds
Day 2: ½ tablet(1mg) twice a day. Continue old meds
Day 3: ½ tablet(1mg) in the morning and 1 tablet(2mg) at night. Continue old meds
Day 4: 1 tablet(2mg) every twelve hours. Continue old meds
Day 5: 1.5 tablets(3mg) every twelve hours. Continue old meds
Day 6: 2 tablets(4mg) every twelve hours. Continue old meds
Day 7: 2 tablets(4mg) every eight hours. Stop your old meds.

Subutex 8mg tablets - 42 tablets every 28 days
Day 8 and thereafter: ½ tablet(4mg)every eight hours

# Slower method

- Taper opioids 10% a week.
- Do prescriptions one week at a time.
- Ok to pause a week if needed.
- Titrate to 90 MED
- Individualize treatment plan

**No OUD/ICD-10 Opioid Dependence**

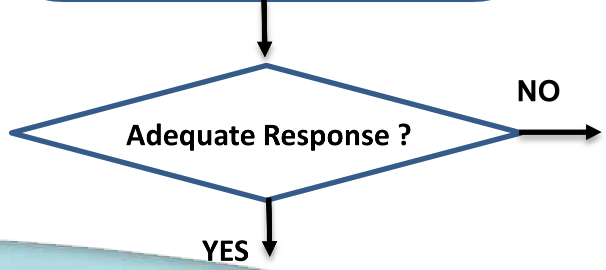
**BUP TDS (BUTRANS)**
For patients transitioning from
≤ 80 mg MEDD*

**Or**

**BUP BF (BELBUCA)**
For patients transitioning from
≤ 160 mg MEDD

**Or**

**BUP/NAL (SUBOXONE) or BUP (SUBUTEX)**
For patients transitioning from
≥ 160 mg MEDD




**NO**

Try the next buprenorphine formulation in the listed order. If patient fails all three buprenorphine formulations, consider tapering off buprenorphine and use of alternate pain management modalities.

**YES**

**Continue Treatment**

**OUD/ICD-10 Opioid Dependence**

**BUP/NAL (SUBOXONE, first-line) or BUP (SUBUTEX, if a contraindication to naloxone)**

# Bernese Method – Bup/naloxone

Outpatient microdosing induction schedule for buprenorphine–naloxone

- Day 1: 0.5 mg once a day
- Day 2: 0.5 mg twice a day
- Day 3: 1 mg twice a day
- Day 4: 2 mg twice a day
- Day 5: 3 mg twice a day
- Day 6: 4 mg twice a day
- Day 7: 12 mg (stop other opioids)

# Medication formulation tips

- Buccal film and transdermal patch – pharmacy many need to order
- Many insurances have a preferred formulation
- If you expect titration, Rx at least two weeks supply and see patient weekly – allows time for pharmacy to stock the medication.
- First rx to a pharmacy you know and can easily communicate with.

Buprenorphine Products:

| Generic Name | Brand Name | Formulation | FDA-Approved Indications | Bio-availability | Elimination Half-Life |
|---|---|---|---|---|---|
| Buprenorphine | Butrans® (VANF) | Transdermal delivery system Available in 5, 7.5, 10, 15 and 20 mcg/hr patches | Management of pain severe enough to require around-the- clock, long-term opioid treatment | ~15% | ~26 hours |
| Buprenorphine | Belbuca® (VANF) | Buccal film Available in 75, 150, 300, 450, 600, 750, 900 mcg films Max dose: 900 mcg every 12 hours | Management of pain severe enough to require around-the-clock, long-term opioid treatment | 46 to 65% | 11.2 to 27.6 hours |
| Buprenorphine and naloxone | Suboxone® (VANF) | Sublingual tablet and film Available in 2-0.5 and 8-2 mg SL tabs and 2-0.5, 4-1, 8-2, and 12-3 mg film Target maintenance dose for OUD is 16 – 24mg/day | Used off-label for pain management. FDA approved for the treatment of opioid dependence (a.k.a. ICD-10 F11.2x opioid dependence or DSM-5 OUD). | ~30% (tab)<br>~36% (film)* | 24 to 42 hours |
| Buprenorphine | Subutex® (VANF) | Sublingual tablet Available in 2mg and 8 mg SL tablets Target maintenance dose for OUD is 16 – 24mg/day | Used off-label for pain management. FDA approved for the treatment of opioid dependence (a.k.a. ICD-10 F11.2x opioid dependence or DSM-5 OUD). | ~30% (tab) | 24 to 42 hours |

# Perioperative management

*Expert opinion*

- Maximize adjunctive therapies & regional anesthesia
- Spread out doses to TID if bup/naloxone
- Uptitrate buprenorphine dose (max 32mg/day) OR
- Add short-acting full agonist opioids during periop period
- Consider pain service consult if available

*Relapse rates high with rapid tapering if OUD

# Billing for Chronic Pain Management

- Medicare Chronic Pain Management and Treatment Services (CPM)
  - Must use ORT initially to screen for opioid misuse risk
  - Must monitor with one of several pain assessment tools
  - May be initiated at time of diagnosis
  - Visits at least 30 min, provider must be physician or APP

| WHAT PROVIDER CODES | Services* | What FQHC bills to CMS | CMS/ Medicare 2023 Fees |
|---|---|---|---|
| HCPCS G3002 | Initial face-to-face CPM visit by a physician or QHP; first 30 minutes; per calendar month | G0511 | $77.94 |
| HCPCS G3003 | Each add'l 15 minutes of CPM by a physician or QHP, per calendar month | | |
| The extension of the COVID-19 PHE flexibility allows FQHCs to furnish CPM services, through December 31, 2024, using audio and visual telehealth telecommunications technology. | | G2025 | $98.27 |

# Resources


- Drug Overdose Deaths in the United States, 2002–2022, CDC; https://www.cdc.gov/nchs/products/databriefs/db491.htm
- Drug Scheduling, DEA; https://www.dea.gov/drug-information/drug-scheduling.
- Dowell D et al. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 Recommendations and Reports / November 4, 2022 / 71(3);1–95. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm
- VA/DoD Clinical practice guideline for the use of opioids in the management of chronic pain, May 2022; https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOpioidsCPGPatientSummary.pdf
- Poliwoda S et al. Buprenorphine and its formulations: a comprehensive review. Health Psychol Res. 2022; 10(3): 37517. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9392838/
- Buprenorphine formulations for chronic pain management in patients with opioid use disorder or on long-term opioid therapy with physiologic tolerance, Rev. April 2023; VA Pharmacy Benefits Management Services. (More recent update March 2024 at https://www.va.gov/formularyadvisor/DOC_PDF/CRE_Buprenorphine_for_Chronic_Pain_MAR_2024.pdf)
- Jonan A et al. Buprenorphine Formulations: Clinical Best Practice Strategies Recommendations for Perioperative Management of Patients Undergoing Surgical or Interventional Pain Procedures, Pain Physician 2018; 21:E1-E12; https://www.painphysicianjournal.com/current/pdf?article=NTAwMQ%3D%3D&journal=109
- Perioperative Pain Management Guidance for Patients on Chronic Buprenorphine Therapy Undergoing Elective or Emergent Procedures Supplemental Information February 2022, VA Pharmacy Benefits Management Services; https://www.va.gov/formularyadvisor/DOC_PDF/CRE_Buprenorphine_Perioperative_Guidance_Supplemental_Information_FEB2022.pdf
- FQHC Requirements for Medicare Chronic Pain Management and Treatment Services (CPM), NACHC; https://www.nachc.org/wp-content/uploads/2023/07/Reimbursement-Tips_CPM.pdf

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