Controlled but Necessary: Clinical Use of Schedule II Medications in Pediatric Care

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Disclosures

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  - No conflicts of interest to disclose
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Objectives

- Review the mechanism of action, therapeutic uses, and risks associated with commonly prescribed schedule II medications and opioids
- Discuss DEA regulations, prescribing restrictions, and state-specific laws affecting the use of Schedule II medications in pediatric practice
- Explore alternative therapies and multimodal approaches to pain management to minimize reliance on Schedule II medications

CLINICAL REVIEW OF COMMONLY PRESCRIBED SCHEDULE II MEDICATIONS AND OPIOIDS

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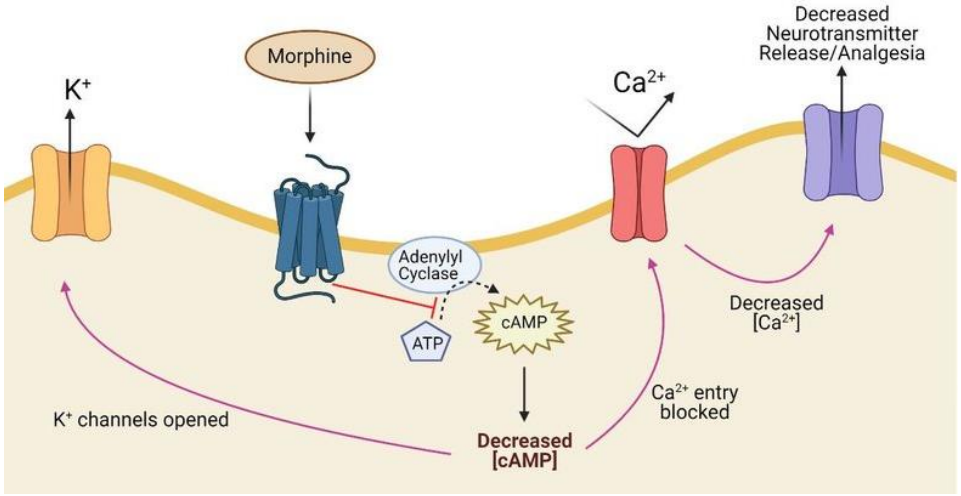
Schedule II Medications

- Drugs, substances, or chemicals with a high potential for abuse, with use potentially leading to severe psychological or physical dependence
- Specific medications
  - Fentanyl
  - Hydrocodone +/- acetaminophen
  - Hydromorphone
  - Methadone
  - Morphine
  - Oxycodone +/- acetaminophen

Mechanism of Action (MOA)

- Opioids bind to endogenous opioid receptors in the central nervous system (CNS) and throughout the body
- CNS binding inhibits ascending pain pathways and alters perception and response to pain
- Receptors found throughout the body which contributes to adverse effects



Fentanyl citrate injection [prescribing information]. Lake Forest, IL: Hospira Inc; December 2023.

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Adverse Drug Reactions (ADRs)

Neurologic
- Somnolence
- Dizziness

Respiratory
- Respiratory depression

Cardiac
- Bradycardia

Gastrointestinal
- Nausea
- Vomiting
- Constipation*

Genitourinary
- Urinary retention

Immune
- Redness
- Hives
- Itching

*Tolerance can develop to analgesia, respiratory depression, and euphoria but less likely to develop to constipation

Fentanyl citrate injection [prescribing information]. Lake Forest, IL: Hospira Inc; December 2023.

Black Box Warnings (BBW)

- Addiction, abuse, and misuse can lead to overdose and death
- Respiratory depression – can be fatal
- Crushing, dissolving, or chewing of long-acting forms may lead to fatal doses
- Concurrent benzodiazepine or other CNS depressants can increase sedation, respiratory depression, and death

Fentanyl citrate injection [prescribing information]. Lake Forest, IL: Hospira Inc; December 2023.

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Drug	Dosage Forms	Pearls
Fentanyl	IV, patch	• Patches for chronic pain, not for patients that are opioid naive, change q72h • Interaction with CYP3A4 inhibitors • Chest wall rigidity with rapid administration of IV
Hydrocodone +/- acetaminophen	Oral solution, tablet	• Caution with concurrent acetaminophen to stay under total daily limits • Interaction with CYP3A4 inhibitors
Hydromorphone	Oral solution, tablet (IR & ER), IV	• High potency

Fentanyl citrate injection [prescribing information]. Lake Forest, IL: Hospira Inc; December 2023.
Hydrocodone bitartrate and acetaminophen oral solution [prescribing information]. Allentown, PA: Genus Lifesciences Inc; March 2024.
Dilaudid (hydromorphone) [prescribing information]. Pickering, Ontario, Canada: Purdue Pharma; August 2023.

Drug	Dosage Forms	Pearls
Methadone	Oral solution, tablet, IV	• BBW: QT prolonging, arrhythmias • Variable half-life • Avoid serotonergic drugs • Major CYP3A4 substrate
Morphine	Oral solution, tablet (IR/ER), ER capsule, IV	• ADR: histamine-induced pruritus more common • Renally cleared
Oxycodone +/- acetaminophen	Oral solution, tablet (IR, CR)	• BBW: CYP3A4 inhibitors • Renally cleared • Caution with concurrent acetaminophen to stay under total daily limits

Methadone Hydrochloride Intensol [prescribing information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc; April 2025.
Morphine sulfate injection [prescribing information]. Lake Forest, IL: Hospira Inc; October 2021.
Oxycodone hydrochloride and acetaminophen tablet [prescribing information]. Newtown, PA: KVK-Tech Inc; January 2024.

Clinical Pearls

- Long acting or controlled release formulations are designed to be given on a regular schedule, not “AS NEEDED”
  - Often used in patients with renal dysfunction due to less accumulation of active metabolites
- Always individualize therapy based on patient specific situation

Hadland SE, et al. *Pediatrics*. 2024.

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Clinical Pearls

- Pediatric patients at a higher risk of side effects with errors, verify:
  - Weight based vs flat dosing
  - Order rounding appropriate
  - Dose can be measured
  - Dosage form appropriate for patient age

Hadland SE, et al. *Pediatrics*. 2024.

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Organ Function Dose Adjustments

- Renal
  - May need to adjust dose based on renal function
    - Morphine
    - Oxycodone
- Hepatic
  - May need to adjust dose based on hepatic function

Fentanyl citrate injection [prescribing information]. Lake Forest, IL: Hospira Inc; December 2023..
Dilaudid (hydromorphone) [prescribing information]. Pickering, Ontario, Canada: Purdue Pharma; August 2023.
Morphine sulfate injection [prescribing information]. Lake Forest, IL: Hospira Inc; October 2021.

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Opioid Conversion Resources

- Ohio Board of Pharmacy Conversion Calculator
  - Ohio Board of Pharmacy
- MD Calc©
  - Opiate Conversion Calculator
- Micromedex©
  - Opioid Equianalgesic Estimate - MICROMEDEX
- LexiDrug©
  - Opioid Conversion Table (Pediatric and Neonatal Lexi-Drugs) - UpToDate® Lexidrug™

Opioid Conversions

1. Calculate total daily dose of opioid
2. Use table to convert to equianalgesic dose
3. Calculate 25-50% dose reduction
    - Reduces risk of adverse events and unintentional overdose
    - A greater reduction may be considered for higher daily doses and organ dysfunction
4. Divide daily dose into a daily regimen

Drug	PO	IV
Fentanyl	---	0.1 mg
Hydrocodone	30 mg	---
Hydromorphone	6 mg	1.2 mg
Morphine	30 mg	10 mg
Oxycodone	20 mg	---

Lexi-Drugs [database online]. Lexi-Comp, Inc; June 9, 2025

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Opioid Conversions

EG is a 16-year-old male who is receiving 0.4 mg of IV hydromorphone every 6 hours for acute pain following surgery. What is an equivalent oxycodone regimen?

1. Calculate total daily dose of opioid
   - 0.4 mg every 6 hours IV hydromorphone = 1.6 mg/day
2. Use table to convert to equianalgesic dose
   - 1.6 mg/day IV hydromorphone x (1.2 mg IV hydromorphone / 20 mg PO oxycodone) = 38.4 mg/day oral oxycodone
3. Calculate 25-50% dose reduction
   - 38.4 mg/day oral oxycodone x 25% = 28.8 mg/day oral oxycodone
4. Divide daily dose into a daily regimen
   - 7.5 mg oral oxycodone every 6 hours

Therapeutic Uses

Acute Pain

- Lasting <1 month
- e.g., post-operative

Subacute Pain

- Lasting 1-3 months
- e.g., broken bone

Chronic Pain

- Lasting ≥ 3 months
- e.g., sickle cell

Palliative

- e.g., cancer, transplant (solid organ, BMT)

End-of-Life

Hadland SE, et al. *Pediatrics*. 2024.

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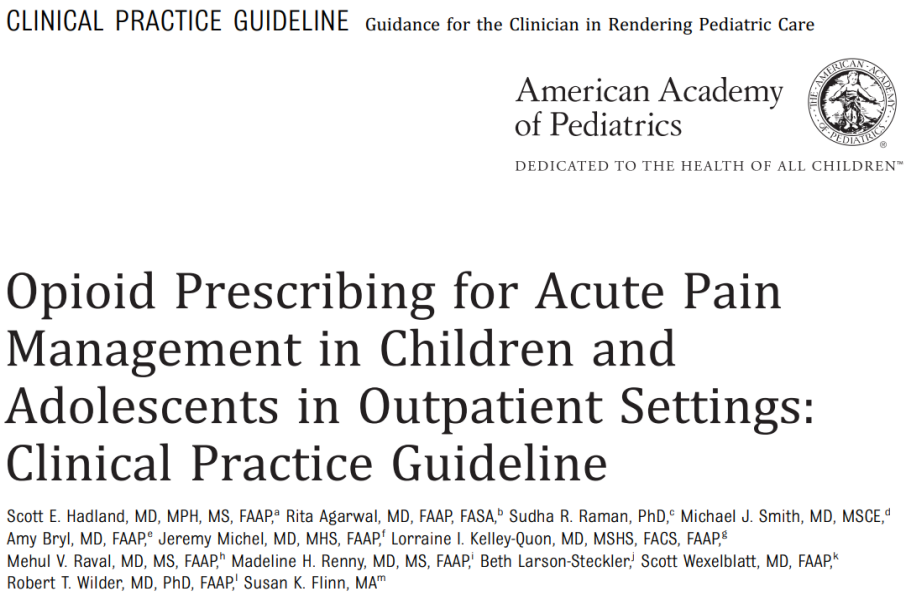
Acute Pain

- American Academy of Pediatrics (AAP) released first clinical practice guidelines in 2024
- Applies to patients <21 years in an outpatient setting



Hadland SE, et al. *Pediatrics*. 2024.

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Acute Pain

- Treat acute pain using a multimodal approach using nonpharmacologic therapies, nonopioid medications, and opioids if needed
- Avoid opioids as monotherapy
- Caution with concurrent use of sedative medications like benzodiazepines
- For treating acute, worsened pain in patients with preexisting chronic pain
  - Prescribe opioids when indicated
  - Utilize other opioid-prescribing clinicians involved in the patient's care
  - Monitor for misuse

Hadland SE, et al. *Pediatrics*. 2024.

Acute Pain

- For mild-moderate pain, nonopioid medications/treatments should be initiated and optimized before considering an opioid
- If the patient has severe pain or severe pain is anticipated, an opioid can be started at the same time as nonopioid therapies
- The use of opioids should be reassessed regularly and weaned as tolerated

Hadland SE, et al. *Pediatrics*. 2024.

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Acute Pain After Surgery

- JAMA Surgery published "Guidelines for Opioid Prescribing in Children and Adolescents After Surgery" in 2021
- Contains recommendations for procedures that have evidence for opioid-free recovery and when enteral analgesic administration can be utilized
- If medications are needed at discharge, non-opioid monotherapy or in conjunction with an opioid is recommended
- Ketorolac has been shown to reduce pain and opioid usage

JAMA Surgery

Kelley-Quon LI, et al. *JAMA Surg*. 2021

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Acute Pain After Surgery

Surgical Procedures With Evidence for Opioid-Free Recovery

Procedure	LOE[a]
Opioid-free recovery recommended [b]	
General surgery	
Inguinal hernia repair[129–131]	2,4
Umbilical/epigastric hernia repair[12]	3
Pyloromyotomy[132,133]	3,4
Soft tissue excision	5[d]
Pectus bar removal[134]	5[d]
Central line placement	5[d]
Otolaryngology	
Myringotomy[135,136]	2
Urology	
Circumcision or hypospadias repair[137]	3
Meatotomy	5[d]
Opioid-free recovery possible [c]	
General surgery	
Laparoscopic procedures (eg, appendectomy[138,139])	4
Nuss procedure[140,141]	4
Otolaryngology	
Tonsillectomy/adenoidectomy[142–146]	2,4
Cochlear implant[147]	4
Plastic surgery	
Operative burn debridement[148]	4
Urology	
Orchidopexy[149,150]	3,4
Pyeloplasty[151]	4
Orthopedic surgery	
Anterior cruciate ligament repair[152]	4
Hip or femoral surgery[153]	3

Kelley-Quon LI, et al. *JAMA Surg*. 2021

Acute Pain After Surgery

Surgical Procedures With Evidence Favoring Enteral Analgesic Administration to Decrease Opioid Administration[a]

Surgical specialty	Procedure(s)	LOE[b]
General surgery	Lower abdominal incisions, appendectomy[129,154,155]	2
Ear, nose, and throat	Tonsillectomy/adenoidectomy, myringotomies[142,156–161]	2,4
Plastic surgery	Palatoplasty[162,163]	2,4
Urology	Hypospadias repair[164]	2
Orthopedic surgery	Outpatient procedures (ie, arthroscopy, pinning, etc)[165]	2
Neurosurgery	Craniectomy[166]	4
Ophthalmology	Strabismus repair[167]	2

Kelley-Quon LI, et al. *JAMA Surg*. 2021

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Chronic Pain

- WHO Guidelines on the management of chronic pain in children
  - Focuses on non-pharmacologic methods to use in conjunction with pharmacologic
  - For chronic pain associated with life-limiting conditions, morphine may be given

World Health Organization

Guidelines on the management of chronic pain in children. Geneva: World Health Organization; 2020.

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DEA REGULATIONS, PRESCRIBING RESTRICTIONS, AND STATE-SPECIFIC LAWS

*Disclaimer: Laws very based on state, please refer to supervisor/manager, workplace policy, and state laws

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Drug Enforcement Agency (DEA)

- Created under the Controlled Substances Act of 1970
- Reports to the Attorney General, separate from the FDA
- Focus on enforcing drug laws like controlled substance laws
- Regulates drug procurement and distribution
- Determines standards for prescription requirements
- Requires prescribers, pharmacies, and healthcare facilities to register

Ortiz NR, et al. [Internet]. Treasure Island (FL): StatPearls Publishing; 2025
Controlled Substances Act, Title 21, U.S.C.

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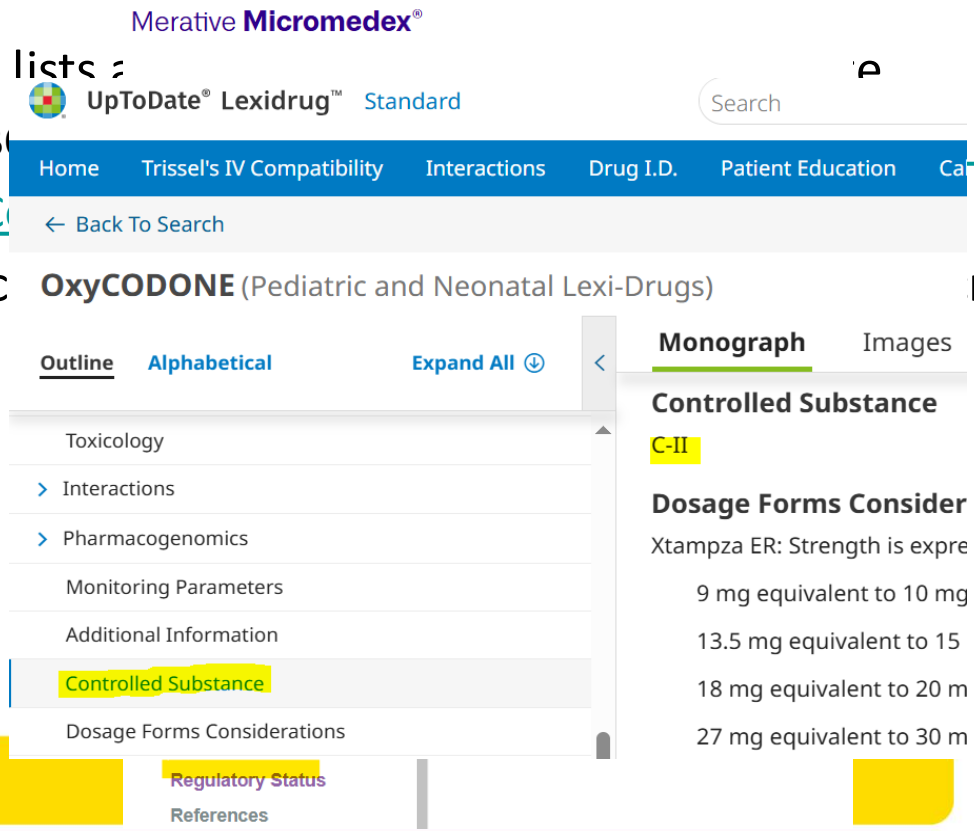
Schedule II Medications

- DEA determines drug classification and maintains definitions of controlled substances
  - Schedule I – V, legend, or over-the-counter
- US Attorney General may add, delete, or reschedule substances by obtaining scientific and medical recommendations from the FDA
- Definition:
  - Drugs, substances, or chemicals with a high potential for abuse, with use potentially leading to severe psychological or physical dependence
  - Considered to be dangerous drugs

Ortiz NR, et al. [Internet]. Treasure Island (FL): StatPearls Publishing; 2025
Controlled Substances Act, Title 21, U.S.C.

Schedule II Medications

- Complete lists a e
  - Ohio B | Ohio Laws
  - DEA: C
- Federal sc romedex© for individual



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Food and Drug Administration (FDA)

- Regulates the safety and efficacy of drugs
  - Includes controlled substances
  - Some overlap with DEA
- Can compile scientific data and data from new drug applications to submit to DEA for scheduling
- Maintains Risk Evaluation Mitigation Strategies (REMS) for opioid analgesics

Ortiz NR, et al. [Internet]. Treasure Island (FL): StatPearls Publishing; 2025
Controlled Substances Act, Title 21, U.S.C.

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Risk Evaluation Mitigation Strategies (REMS)

- REMS is a risk management program required by FDA to ensure that the benefits of a drug outweigh the risk
  - Goal is to mitigate the risks of addiction, abuse, and misuse
- Applies to all brand and generic opioid analgesics that are intended for use in the outpatient setting
  - Updated 10/2024
  - Previously applied to specific products
- Approved Risk Evaluation and Mitigation Strategies (REMS)

"Opioid Analgesic REMS." U.S. Food and Drug Administration. 30 May 2025.

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Risk Evaluation Mitigation Strategies (REMS)

- Provides free REMS-compliant accredited continuing education (CE) for healthcare providers who prescribe or are involved in the management of patients with pain
  - Free CE available on website
    - Opioid Analgesic REMS - Home
  - Recommended to complete one CE annually but not required

"Opioid Analgesic REMS." U.S. Food and Drug Administration. 30 May 2025.

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State Boards

- Regulates the practices of pharmacy and providers authority to prescribe
  - Inpatient and outpatient prescribing
  - Who can prescribe
    - Differences between MD/DO, APRN-CNP, and PA-C
- DEA maintains list of Schedule II medications, but federal law allows states to regulate a medication more strictly if they choose
  - E.g., gabapentin not controlled federally or in Ohio, but in West Virginia it is a schedule V

Ohio Rev. Code § 3719.44

Outpatient Prescribing of CII for APRN-CNP

- Must be registered with DEA
- May prescribe CII only if all the following are met:
  - Patient has a terminal condition
  - Physician initially prescribed the substance for the patient
  - Prescription is for an amount that does not exceed the amount necessary for the patient's use in a single, **72-hour period**
- Exceptions:
  - APRN-CNP working at a registered hospital or health system, etc.
  - Refer to law or direct supervisor/organizational policies

Ohio Rev. Code § 4729.46
Ohio Rev. Code § 4729:5-1-02
Ohio Rev. Code § 4723-9-10

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Outpatient Prescribing of CII for PA-C

- Must be registered with DEA
- May prescribe CII only if all the following are met:
  - Patient has a terminal condition
  - Physician initially prescribed the substance for the patient
  - Prescription is for an amount that does not exceed the amount necessary for the patient's use in a single, **24-hour period**
- Exceptions
  - PA-C working at a registered hospital or health system, etc.
  - Refer to law or direct supervisor/organizational policies

Ohio Rev. Code § 4729.46
Ohio Rev. Code § 4730.41
Ohio Rev. Code § 4729:5-1-02
Ohio Rev. Code § 4730.411

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Inpatient Prescribing of CII

- Outpatient restrictions on prescribing CII medications do not apply to APRN-CNP or PA-C within an inpatient hospital setting unless otherwise stated by hospital policy
- Hospital DEA numbers utilized in combination with internal code assigned

Ohio Rev. Code § 4729.46
Ohio Rev. Code § 4730.41
Ohio Rev. Code § 4729:5-1-02 ; 3-15
Ohio Rev. Code § 4730.411
Ohio Rev. Code § 4723-9-10

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Ohio Automated Rx Reporting System (OARRS)

- OARRS is a tool to track the dispensing of controlled drugs to patients
- Designed to monitor dispensing information for suspected abuse or diversion
- Can help identify high-risk patients
- OARRS - Ohio Automated Rx Reporting System

Ohio Administrative Code § 4723-9-12
Ohio Administrative Code § 4730-2-10
Ohio Administrative Code § 4731-11-11

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Ohio Automated Rx Reporting System (OARRS)

Ohio Board of Pharmacy

WHEN TO CHECK OARRS – PRESCRIBERS

Ohio law and rules require a prescriber to check OARRS in the following circumstances:

1. Before prescribing or personally furnishing an opioid analgesic or benzodiazepine to a patient.[1]
2. When the course of treatment with a reported drug ***other than*** an opioid analgesic or benzodiazepine has lasted more than ninety (90) days.[1]
3. When red flags are present.[2]

Ohio Administrative Code § 4723-9-12
Ohio Administrative Code § 4730-2-10
Ohio Administrative Code § 4731-11-11

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Ohio Automated Rx Reporting System (OARRS)

WHEN TO FOLLOW-UP IN OARRS

Ohio law and rules require a prescriber to conduct a follow-up check in OARRS in the following circumstances:

- When treatment with an opioid analgesic or benzodiazepine lasts more than ninety (90) days, OARRS should be reviewed at least every ninety (90) days during course of treatment.
- At least annually following the initial OARRS report when treatment with a reported drug ***other than*** an opioid analgesic or benzodiazepine lasts more than ninety (90) days.

Ohio Administrative Code § 4723-9-12
Ohio Administrative Code § 4730-2-10
Ohio Administrative Code § 4731-11-11

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Prescription of Opioids to Minors

- Before issuing the first prescription an opioid analgesic for a minor, regardless of whether the dosage is modified during that course of treatment, a prescriber shall:
  - Assess whether the minor has ever had, or currently has, mental health or substance abuse disorders
  - Discuss risks with the minor and the minor's parent/guardian
  - Prescriber shall record the consent on a form which shall be known as the "start talking" consent form

Ohio Rev. Code § 3719.061

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Prescription of Opioids to Minors

- Requirements of this section do not apply if:
  - Treatment is associated with a medical emergency
  - Treatment is associated with a surgery, regardless of whether surgery is performed on an inpatient or outpatient basis
  - At time of discharge from a facility or other location
  - Does not apply to treatment rendered in a prescriber's office that is located on the premises of or adjacent to a facility or other location

Ohio Rev. Code § 3719.061

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ALTERNATIVE THERAPIES AND MULTIMODAL APPROACHES TO PAIN MANAGEMENT

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Oral Alternatives

Acetaminophen	Ketamine	Alpha 2 adrenergic agents	Gabapentinoids
Amitriptyline	Duloxetine	Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)	Cyclobenzaprine

Drug/Class	MOA	ADR	Drug Formulation (s)	Uses	Pearls
Acetaminophen Analgesic, nonopioid	Central COX inhibition	Hepatotoxicity	Oral liquid, chewable, tablets, suppository, IV	First-line mild pain	• Counsel on max daily dose (4g) • Check concentrations • Monitor for duplicate combination products
Ketamine General anesthetic	NMDA antagonist-reduces central hyperalgesia	Dysphoria, nystagmus, N/V, tachycardia, hypertension	IV, IM, IN, oral solution, capsules	Acute, postoperative, and chronic pain	• Best at sub-dissociative doses, consider adjunctive antiemetics • RX only

Acetaminophen [prescribing information] Berkeley Heights, NJ, HIKMA 2022.
Ketamine [prescribing information] Pfizer, 2024.

Drug/Class	MOA	ADR	Drug Formulation (s)	Uses	Pearls
Clonidine Alpha-2 Adrenergic	Decrease NE release	Dizziness, drowsiness, bradycardia, ↓BP, dry mouth	Tablets (IR & ER), oral liquid, patch	Procedural sedation, withdrawal, adjunct	• Taper to avoid rebound hypertension • Beware various concentrations • Patch lasts for 5-7 days; do not cut block surface area • RX only
Dexmedetomidine Alpha-2 Adrenergic	Decrease NE release	Bradycardia, ↓BP, dry mouth	IV, intranasal (off-label)		• Lack of respiratory depression • RX only

Mahmous M et al. J. Clin. Med 2020, 9 (9): 2724.

Drug/Class	MOA	ADR	Drug Formulation (s)	Uses	Pearls
Gabapentin Gabapentinoid	Calcium channel modulation; ↑ inhibitory transmission	Sedation, dizziness, mood/ behavioral changes, weight gain	Capsule, oral liquid, tablet (IR,ER)	Neuropathic pain	• Start slow and titrate • Consider wean pending duration • Rx only
Pregabalin Gabapentinoid	Calcium channel modulation; ↑ inhibitory transmission	Sedation, dizziness, mood/ behavioral changes, weight gain	Capsules	Neuropathic pain	• Start slow and titrate • Consider wean pending duration • Rx only

Gabapentin [prescribing information] NY NY, Pfizer. 2024.

Drug/Class	MOA	ADR	Drug Formulation (s)	Uses	Pearls
Amitriptyline Tricyclic antidepressant	Inhibits reuptake of serotonin and NE→ blocks H1, M1, alpha-adrenergic receptors	Fatigue, weight gain, dry mouth, blurred vision, urinary retention, constipation	Tablets	Neuropathic pain, migraines, fibromyalgia	• Consider baseline ECG • Consider wean pending duration • Rx only
Duloxetine SNRI	SNRI → ↑ serotonin & NE in synapses	GI upset, sleep disturbance, mood changes	Capsules (DR)	Neuropathic pain, comorbid anxiety or depression	• Monitor for drug interactions • Analgesic effect can take up to a week • Rx only

Amitriptyline [prescribing information] Durham, NC. Quality Care LLC, 2016.
Duloxetine [prescribing information] Indianapolis, IN, Eli Lily, 2016.

Drug/Class	MOA	ADR	Drug Formulation (s)	Uses	Pearls
Ibuprofen NSAID	COX-1/2 inhibition → ↓ prostaglandins	GI upset, renal dysfunction, bleeding	Capsule, oral liquid, IV, tablet, chewable	Anti-inflammatory, musculoskeletal pain, headaches	• Take with food to decrease GI distress • Dose escalate
Naproxen NSAID	COX-1/2 inhibition → ↓ prostaglandins	GI upset, renal dysfunction, bleeding	Capsule, oral liquid, tablet (DR, ER)		• Longer acting than ibuprofen
Ketorolac NSAID	COX-1/2 inhibition → ↓ prostaglandins	GI upset, renal dysfunction, bleeding	IV, tablet		• 5-day course to prevent renal dysfunction • Consider dose capping • Rx only

Ibuprofen [prescribing information] DailyMed, 2024.
Naproxen [prescribing information] DailyMed, 2024.
Ketorolac [prescribing information] DailyMed, 2024.

Drug/Class	MOA	ADR	Drug Formulation (s)	Uses	Pearls
Cyclobenzaprine Skeletal muscle relaxant	Act on GABA receptors → reduce spasticity and muscle tone	Sedation, weakness, withdrawal symptoms if stopped abruptly	Tablets, capsules	Spasticity-related pain, adjunct for chronic pain	• Consider wean pending duration • Rx only

Cyclobenzaprine [prescribing information] DailyMed 2025.

Topical Alternatives

Oral sucrose	PainEase®	LET gel
EMLA®	Lidocaine	Diclofenac gel
Capsaicin	Menthol	Synera® patch

Agent	MOA	ADRs	Formulation (s)	OTC vs Rx	Pearls
Oral sucrose	Sweet taste → endogenous opioid pathway	Rare choking; caution preterm	24% oral liquid, 0.05–0.5 mL	Hospital use	Best for brief procedures; lasts only minutes
PainEase®	Vapocoolant cooling, counter-irritant	Stinging, rare frostbite	Spray 4–10 seconds until blanch	OTC	Immediate, brief effect; best for needle sticks (≥3 yo); not "sterile"
Lidocaine, epinephrine, tetracaine gel (LET)	Block Na+, epi vasoconstricts	Local blanching; rare systemic toxicity	Compounded gel, apply 20–30 min	Rx	For non-mucosal lacerations; avoid end-arterial sites

Saccharum officinale (sucrose) pellets [package insert]. DailyMed, 2010.
PainEase® [prescribing information] DailyMed, 2025.
LET [prescribing information] DailyMed, 2024.

Agent	MOA	ADRs	Formulation (s)	OTC vs Rx	Pearls
EMLA® cream	Lido + Prilo block Na+	Blanching, erythema; rare methemoglobinemia	2.5%/2.5% cream and gel, dwell ~60 min	Rx	Plan ahead for dwell; follow dosing limits; avoid broken skin
Lidocaine	Na+ channel blocker	Local irritation; systemic toxicity if large area	OTC 4% creams, Rx 5% patch	Both	OTC ≥12 yo (data for > 3yo); avoid large/broken areas
Diclofenac	COX inhibition → ↓ prostaglandins	Dermatitis; systemic NSAID risks	1% gel, adult labeled-dosing; solution, patch (Flector®)	OTC (gel) RX (patch)	Gel Not FDA-approved <18 yo (off-label); patch > 6 yo

EMLA® [prescribing information] DailyMed, 2024.
Lidocaine topical [prescribing information] DailyMed, 2025.
Diclofenac topical [prescribing information] DailyMed, 2025.

Agent	MOA	ADRs	Formulation (s)	OTC vs Rx	Pearls
Capsaicin	TRPV1 agonist, ↓ substance P	Burning, erythema, cough	Cream 0.025–0.1%; patch 0.025-4%, liquid 0.075%, lotion 0.025-0.035%	Both	Consider >8yo; tolerability limits use
Menthol	TRPM8 agonist → cooling	Irritation; avoid broken skin, heat pads	Creams, gels, patches	OTC	Minimum 2yo; avoid strong vapors near infants
Synera® patch	Lidocaine + Tetracaine + warming → ↑ penetration	Erythema, edema; rare burns	Single-use warming patch, 20–30 min	Rx	Approved ≥3 yo; venipuncture or derm procedures; monitor skin

Capsaicin Topical Analgesic [prescribing information] Daily Med. 2024.
Menthol, [prescribing information], DailyMed, 2025.
Synera patch [prescribing information]. Chicago, IL: Braun B PharmaCare 2025.

Non-Pharmacological Management

Acupuncture	Temperature	Massage	Hypnosis / Hypnotherapy
Feed / Swaddle	Rehabilitation • Occupational therapy • Physical therapy	Cognitive Behavioral Therapy (CBT)	Distraction / Relaxation

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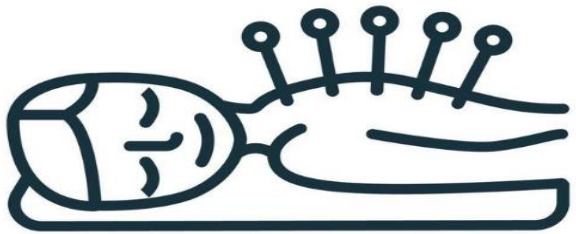
Acupuncture

- Definition: Fine needles at specific points to reduce pain
- Uses: Chronic pain, headaches, musculoskeletal, procedural pain



Acupuncture Supporting Literature

- Evidence quality- Low
- 1335 articles
  - Positive results for chronic pain
  - 5 able to be reviewed: 2 case series, 2 single arm, 1 randomized clinical trial
  - Limitations for study design and sample size

Bissoto J et al. Journal of Pediatrics 2024.

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Temperature- Cold or Heat

- Definition: Using ice packs or warm compresses for pain relief
- Uses: Cold: acute swelling or injury Heat: muscle spasms, stiffness

Cold/Hot Supporting Literature

- Evidence quality: Low to moderate
- Parallel-group randomized controlled design
  - 117 children (7-12 yo)
  - Dry heat, dry cold prior to blood sampling
  - Both applications effective but dry heat had decreased anxiety

Cil, M et al. Journal of Pediatric Nursing 2023.

Massage

- Definition: Manual technique involving systemic manipulation of soft tissues to reduce pain perception, promote relaxation, improve circulation and emotional well-being
- Uses: Adjunctive for post operational, acute procedural, chronic pain

Massage Supporting Literature

- Evidence quality: Low to moderate
- Randomized controlled trial in oncology
  - 23 patients enrolled (1-18 yo)
  - 2- period cross over design
- Meta-analysis for neonatal/infant procedural pain
  - 11 studies (77 neonates)
  - Improved pain response, cry duration, oxygen saturation, heart rate

White et al, Journal of Pediatric Oncology Nursing, 2009.
Liu et al. Medicine 2022.

Hypnosis

- Definition: Guided relaxation and imagery to alter pain perception
- Uses: Procedural pain, headaches, abdominal pain, anxiety-related pain

Hypnosis Supporting Literature

- Evidence quality: Moderate
- 11 meta-analysis
  - Include children and adolescents
  - Support larger effects seen on children rather than adults

Schnur, J et al. Contemp Hypn 2008.

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Physical Therapy

- Definition: Structured activity to improve strength and circulation
- Uses: Chronic pain, rehabilitation, prevent deconditioning

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Occupational Therapy

- Definition: Therapy to restore function and coping
- Uses: Post-op recovery, chronic syndromes, mobility issues

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Rehabilitation Supporting Literature

- Evidence quality: Low-Moderate
- Longitudinal study intensive rehabilitation
  - 77 adolescents 10-18 yo
  - Measurements at 3 time points (pre, first week, discharge, 3 months post)
  - Improvement in functional disability, pain, depressive symptoms, physical measures, and fear of pain

Weiss KE, et al. Clin J Pain 2024.

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Feeding and Swaddling

- Definition: Comforting measures (i.e. breastfeeding, skin-to-skin contact)
- Uses: Neonatal and infant procedures (heel stick, immunization, venipuncture)

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Feeding and Swaddling Supporting Literature

- Evidence quality: High
- 4 published breastfeeding systemic reviews
- 10 published reviews of “sweet solutions”

Harrison D, et al. PAIN Reports 2023.

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Cognitive Behavioral Therapy (CBT)

- Definition: Psychological approach focusing on changing pain related thoughts, behaviors, emotional response
- Uses: Chronic pain, anxiety-associated, functional pain syndromes

CBT Supporting Literature

- Evidence quality: High
- Cochrane and systemic reviews
  - 1739 patients (2- 18 yo) with chronic pain
  - 11 studies
  - Improvements in pain reduction and quality of life

Checa-Penalver, A et al. Children 2024.

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Distraction and Relaxation Techniques

- Definition: Using play, music, virtual reality, breathing exercises, guided relaxation to shift focus
- Uses: Procedural pain (venipuncture, dressing changes), acute pain, anxiety-related

Distraction and Relaxation Supporting Literature

- Evidence quality: Moderate to high
- Randomized Clinical Trial
  - 107 patients (10-21yo) PIVC placement and virtual reality
  - Results: Decreased patient and caregiver anxiety and pain
- Meta analysis
  - < 22yo
  - 13 treatment sites with similar treatment criteria
  - Results: Improvement in mean pain intensity, disability, missed days of school, anxiety, depression

Gold, J et al. JAMA network 2021.
Claus, B et al. Pain 2022.

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Intervention	Definition & Uses	Key Findings
Acupuncture	Insertion of fine needles to modulate pain; used in chronic pain, headaches	Limited pediatric evidence; small studies suggest benefit in headaches & post-op pain
Cold/Heat	Application of cold or heat packs for localized pain relief	Effective for musculoskeletal pain, IV procedures, and post-op pain
Massage	Manual manipulation of soft tissues to promote relaxation and pain relief	Some evidence for postoperative and cancer pain relief; low-risk intervention
Hypnosis/Hypnotherapy	Guided relaxation and focused attention to alter pain perception	Strong RCT evidence for needle procedures, cancer-related pain, and anxiety reduction
Movement/Exercise	Gentle physical activity or stretching to improve mobility and decrease stiffness	Strong evidence for rehabilitation in chronic pain, cancer, and post-surgical recovery
Hypnosis/Hypnotherapy	Guided relaxation and focused attention to alter pain perception	Strong RCT evidence for needle procedures, cancer-related pain, and anxiety reduction
Feed/Swaddle	Comforting techniques (feeding, swaddling, non-nutritive sucking)	Strongest evidence in neonates; reduces procedural pain during heel lance, venipuncture
Rehab (OT/PT)	Therapeutic exercises, mobility, and function-focused interventions	Effective in improving function and reducing pain-related disability in chronic pain
CBT	Psychological therapy targeting thoughts, emotions, and behaviors related to pain.	High-quality evidence for reducing chronic pain, disability, and anxiety.
Distraction/Relaxation	Use of play, music, VR, breathing to shift focus away from pain.	Well-supported for acute procedural pain and anxiety reduction.

Multimodal Approach

- Opioid sparing
- Combine opioids with other medications, use lowest effective dose, shortest duration
- Narcan for high-risk pediatric patients
- Cognitive-Behavioral
- Psychological and physical

Summary

- Pediatric pain management requires individualized therapy
- Balance effectiveness vs safety
- Consider multimodal strategies to minimize risks
- Monitor closely for adverse effects

Resources

- Meg Foundation For Providers | Meg Foundation
- IASP – PERC* International Association for the Study of Pain: Home
- Train Pain Academy Resources – Train Pain Academy
- ChildKind International Homepage | ChildKind International
- Pediatric Pain Listserv LISTSERV 16.0 - PEDIATRIC-PAIN List at LISTSERV.DAL.CA
- Apps (provider and patient)

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* PERC (Pain Education Resource Center)

Key Takeaways

- Schedule II drugs have risks that should be evaluated
- Ohio laws assist in reducing opioid misuse and protecting pediatric patients
- Use multimodal and non-opioid alternative when possible
- Use of prescription monitoring programs and continual education enhances patient safety

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