A PHYSICIAN'S GUIDE TO

Opioid Use in the Lactating Mother

2021 update

This is a practice guideline to improve pain management practices for new and lactating mothers in both the inpatient and outpatient setting. It is based primarily on the recommendations and practice parameters of the American College of Obstetricians and Gynecologists (ACOG), the U.S. Food and Drug Administration (FDA), American Academy of Pediatrics (AAP), and the Academy of Breastfeeding Medicine (ABM). (*See references on page 6 for links to statements.*)

Why Focus ON OPIOID USE IN THE LACTATING MOTHER?

There is great inconsistency in the management of lactating patients with pain management needs, as well as appropriate opioid dosages to minimize risk to the breastfeeding infant. Focus on this issue is fitting for the following reasons:

- **Lactating mothers may be prescribed opioid medication to control pain after a cesarean section or another painful surgery.** Pain management is critical to the postpartum or post-surgical mother and can impact breastfeeding success. Clinicians and patients alike seek to ensure appropriate use of opioids to manage pain and also keep the neonate safe.[FAH]
- **A safety alert has been issued by the U.S. Food and Drug Administration (FDA) that strengthened the warning against prescribing codeine or tramadol for nursing mothers.** Codeine and tramadol are not recommended because the breastfed infant could experience adverse effects from exposure to the opioid analgesics, including difficulty nursing, respiratory complications, and excessive somnolence.[FDA1]
- **The safety of the infant is critical.** Regardless of the opioid selected, the AAP, ABM, ACOG, and FDA recommend nursing mothers taking opioids closely monitor their infants for opioid-related adverse effects.[FDA1, ACO1, SAC, REE, MAR]
- **Clarity is needed among providers regarding medication choices.** A regularly scheduled non-opioid is the first choice for pain management in a lactating mother. Opioids, if needed, should be opioids that are not formulated in combination with other analgesic medications like acetaminophen or ibuprofen.[ACO1, REE, MAR, FAH] Generally, the lowest dose of oxycodone may be preferred as an oral option over hydrocodone, hydromorphone, and morphine.[LAN]
- **The term "opioid" is the preferred terminology for prescription pain medication.** As as opposed to "narcotic" or "pain pill," this terminology is clinically specific and avoids confusion.[CDC]

WHAT'S INSIDE?

MEASUREMENT & GOALS

The goal of this CPM is to monitor adherence to opioid prescribing guidelines and pattern of use in iCentra for postpartum conditions.

Proposed Plan: Monitor as a watch metric

- Utilize the system Opioid Stewardship Dashboard as source for data. Filter down to *Women's Health Clinical Area* (this is currently available as filter for this report).
- Review data quarterly in OBDT.
- Monitor outliers to prescribing >=90 MME (this is the current information in the system Opioid Stewardship Dashboard).

Indicates an Intermountain measure

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WHERE TO GO WITH QUESTIONS

For additional questions about safely prescribing opioids to lactating mothers, see:

- The lactation service in your facility
- A board-certified lactation consultant. To locate one in your area, go to www.ilca.org
- Brigg's Drugs in Pregnancy and Lactation via Lexicomp®
- Drugs for Pregnant and Lactating Women via ClinicalKey®
- MotherToBaby supported by the Organization of Teratology Information Specialists (OTIS)
- LactMed database

KEY RECOMMENDATIONS

These recommendations support the provider's ability to prescribe confidently and communicate effectively with the patient.

How to prescribe

- Consider the following pain regimen for lactating mothers:
  - **Prescribe regularly scheduled alternating doses of acetaminophen and a nonsteroidal anti-inflammatory drug (NSAID) for at least 3-5 days after the procedure.** Review recommendations for dosing in **Table 1** on page 3.
  - **Implement a multimodal approach to minimize opioid use.** A multimodal approach includes nonpharmacologic options (such as ice) and non-opioid medications (such as acetaminophen and NSAIDs).[ACO1, REE, MAR, FAH] Note that 1 in 300 opioid-naïve patients will become persistent opioid users following cesarean birth.[ACO1] Accordingly, thoughtful prescribing of opioids alongside other analgesics like acetaminophen and NSAIDs is critical.[ACO1, REE, MAR, FAH]
  - **If an opioid is needed, a careful discussion with the patient about the risks and benefits is necessary.** Prescribe the lowest dose for the shortest time to relieve their pain.[ACO1, SAC,REE, FAH]

How to counsel the patient

- Both patients and providers may be concerned about how the patient can safely breastfeed while using opioids. Key messages to the patient include:
  - **Keep breastfeeding.** Breast milk is the best food for the baby, and if the mother stops breastfeeding, she risks losing her milk supply.[AAP1, AAP2]
  - **Non-opioid options are the first-line treatment for pain.** If pain is not well managed, opioids may be added to the scheduled non-opioids to control breakthrough pain.[ACO1, REE, MAR, FAH]
  - **Surgical anesthetics (other than opioids) are lower risk medications in lactating mothers** since most are either rapidly eliminated or do not concentrate in human milk.[SAC,REE] Therefore, minimal exposure to these agents is anticipated when a mother wakes up and feels like nursing the infant.[SAC,REE]
  - **Opioids are safe when taken as directed,** with close monitoring of the breastfed infant and mother.[ACO1, REE, MAR, FAH] This is especially important because opioid use during lactation has been associated with central nervous system depression in the infant that may be severe or potentially fatal.[ACO1, SAC, FAH]
  - **The opioid medication should be taken right *before* breastfeeding** to reduce exposure to the nursing infant at subsequent feedings.[FAH]

RECOMMENDATIONS FOR LACTING MOTHERS HAVING SURGERY

- **It is not necessary to pump and dump the milk after surgery** as the anesthesia poses very little risk to the infant. Most anesthetics are rapidly excreted from the body. By the time she is ready to go home, it is safe to resume breastfeeding.
- She may want to pump at these times:
  - **In the days before surgery,** so milk will be available during surgery. All breast milk can be frozen for later use.
  - **Just before going in to the operating room.**
  - **Right after surgery,** in case she doesn't want to breastfeed right away. This will help maintain her milk supply and keep her from getting uncomfortably full.

If she needs a breast pump or has concerns about breastfeeding, she should contact her bedside nurse who can help coordinate a lactation consultation.

DOSING RECOMMENDATIONS

The following dosages, listed in order of preference, are recommended both for mothers who have just delivered and for mothers who have had surgery when their baby is a little older.

TABLE 1. Dosage Recommendations for Select Pain Medications in Lactating Mothers [ACO1, SAC, REE, MAR,9,10,11, NLM, HAL]

Drug*	Dosage*	Notes
Non-opioid analgesics		
Acetaminophen (Tylenol®)	325 - 650 mg by mouth every 4 - 6 hours PRN pain	**Preferred non-opioid pain medication.** For moderate pain, dose may be increased to 1 g every 6 hours. Do not exceed 4 g in 24-hour period. While opioid-acetaminophen combination products should be avoided, account for grams of acetaminophen from these products if they are prescribed.
Ibuprofen (Advil®, Motrin®)	600 - 800 mg by mouth every 6 - 8 hours PRN pain for 10 days	**Preferred non-opioid pain medication.** Take with food. Do not exceed 3.2 g in 24-hour period. Works best if taken in regular intervals.
Opioids		
Oxycodone	2.5 - 10 mg by mouth every 4 - 6 hours PRN pain	**Preferred opioid pain medication.** Titrate based on response. Do not exceed 30 mg in a 24-hour period. AAP does not recommend use in nursing mothers, while ABM and ACOG do not mention a clearly preferred opioid.
Hydromorphone (Dilaudid®)	2-4 mg by mouth every 4-6 hours PRN pain	Titrate based on response. Do not exceed 20 mg in a 24 hour period.
Morphine sulfate IR	5 -15 mg by mouth every 4 - 6 hours PRN pain	Titrate based on response; optimal dosage is influenced by several factors. Contact your clinical pharmacist or Pain Management Services for assistance. While AAP notes morphine may be a safer opioid since metabolism to the active metabolite is not influenced by CYP2D6, ABM and ACOG do not mention a clearly preferred opioid.
Combination opioids		
Hydrocodone-acetaminophen (Hycet®, Lortab®, Norco®)	5 mg by mouth every 4 - 6 hours PRN pain	Titrate based on response. Do not exceed 30 mg for hydrocodone and 4 g for acetaminophen in 24-hour period. If hydrocodone is selected, be sure to remove scheduled doses of acetaminophen that would exceed 4 g recommendation. AAP recommends cautious use in nursing mothers while ABM and ACOG do not mention a clearly preferred opioid.

AAP = American Academy of Pediatrics; **ABM** = Academy of Breastfeeding Medicine; **ACOG** = American College of Obstetricians and Gynecologists; **CYP2D6** = cytochrome P450 2D6 isozyme; **IR** = immediate release; **PRN** = as needed

*For patients with complex pain management needs, please consult your pharmacist or the Acute Pain Service for assistance.

General pharmacotherapeutic approach to pain management in lactating mothers

- **Begin with regularly scheduled doses of acetaminophen and NSAID for at least 3-5 days after the procedure.** If additional pain control is needed, be sure that the quantity of any opioid prescribed balances adequate analgesia with avoidance of unused opioid tablets.[ACO1, REE, MAR, FAH]
- **If pain is not managed with first-line, non-opioid analgesics,** consider adding an opioid as specified in **Table 1** above at the lowest dose and longest frequency possible and titrate based on response.[ACO1, SAC, REE, MAR, FAH] **Immediate-release medications are preferred over extended-release medications.**[ACO1, FAH]
- **If hydrocodone is selected,** try to maintain the dosage to less than 30 mg daily.[REE, MAR, FAH] Be sure to remove scheduled doses of acetaminophen that would exceed 4 g recommendation.
- **Monitor the nursing mother and infant closely for opioid-related adverse effects** (e.g., constipation, difficulty breathing, respiratory depression, somnolence, poor weight gain in the infant).[ACO1, SAC, REE]
- **If opiods are prescribed,** consider adding a prescription for naloxone.

WHAT TO WATCH OUT FOR

Have your patient contact you or the baby's provider if the baby:

- Is much sleepier than normal
- Starts breastfeeding differently
- Is constipated

If the baby is a newborn, have your patient contact you or the baby's provider if the baby:

- Is difficult to arouse for feeding
- Can't suck or feed effectively

If any of the above symptoms are noticed and the patient is unable to reach a provider, they should take the baby to a hospital emergency room.

SAFE DISPOSAL OF OPIOID MEDICATIONS

During the prescription consultation with the patient, the pharmacist should include instructions on how to dispose of leftover or expired opioid tablets.[FDA2, FDA3]

Most leftover or expired medications can be safely discarded in the household trash by mixing the medication with an unpalatable substance (e.g., cat litter, dirt, used coffee grounds,) and sealing it in a plastic bag. However, **opioids should NOT be discarded in this manner.**[FDA3, FDA4] Opioids can result in death with just a single dose if inappropriately ingested.[FDA4] Plus, there is the potential for significant abuse or misuse.[FDA4]

Collection sites that accept opioid medications can be found at useonlyasdirected.org, safepharmacy/drugdisposal, or the U.S. Drug Enforcement Administration. DisposeRx™ packets are also available at most local pharmacies.

If disposal at a collection site is not possible, the FDA recommends that opioids be flushed down the toilet when no longer needed.[FDA2, FDA3, FDA4]

Opioid medications include any drug containing the following names:[FDA4]

- Buprenorphine
- Codeine
- Fentanyl
- Hydrocodone
- Hydromorphone
- Methadone
- Meperidine
- Morphine
- Oxycodone
- Oxymorphone
- Tapentadol
- Tramadol

COUNSELING THE PATIENT


FACT SHEET FOR PATIENTS AND FAMILIES

Breastfeeding and Opioid Pain Medication

What is opioid pain medication?

Why do I need opioid pain medication?

Is it safe to breastfeed while I'm using opioid pain medication?

How can I prepare before surgery?

The following will help breastfeeding patients understand how to breastfeed safely while taking opioid medication. It is recommended that patients be provided with the Intermountain fact sheet *Breastfeeding and Opioid Pain Medicine* to support the provider-patient education discussion. Consider the following:

- **As the patient heals and recovers,** they can take better care of the baby and themselves.
- **The patient should continue breastfeeding** (unless otherwise directed). Breastmilk is the best food for the infant and if breastfeeding is stopped, the patient could lose their milk supply. Opioids have been shown to be safe for the baby when given to breastfeeding patients in lower doses and over short periods of time (4 to 6 days).
- **Use nonpharmacologic and non-opioid analgesic options for pain management related directly to the birthing process whenever possible.** Uterine cramping can be managed by use of heat pads applied to the abdomen plus NSAIDs. Perineal pain can be managed with topical nonpharmacologic agents, topical anesthetics, and oral non-opioid analgesics. Cold packs are also a helpful nonpharmacologic option.[ACO1, FAH]
- **All medications should be taken exactly as directed.** Medications work best if taken at scheduled times. If a non-opioid analgesic is not effective (especially if they have been more active) they may take an opioid.
  - If the patient has just had surgery, their prescription will be given at a level that is safe for the baby.
  - If they have just delivered and have received opioid medication, the risk to the baby is minimal while their milk supply is low. On day 4 or 5 after delivery, most will find their milk to be more abundant and their pain to be adequately managed most of the time with non-opioid analgesics such as acetaminophen (Tylenol®) or ibuprofen (Advil®, Motrin®).
- **The patient should:**
  - **Take the oral opioid medication right before breastfeeding.** Taking the opioid right before starting breastfeeding ensures low levels during the current and subsequent feedings, depending on timing. Opioid plasma concentrations generally peak at 1 to 2 hours after taking an oral dose and are expected to be notably declining at 4 hours post-dose. Accordingly, the patient should avoid breastfeeding at 1 to 2 hours after taking the opioid.[FAH,NLM, HAL]
  - **Call their provider if they still need regular doses of prescription medication or if the pain gets worse after one week.**
  - **Check with their baby's pediatrician before taking ANY additional pain medication prescribed by another doctor, dentist, or other clinician.** The baby's provider can let them know if it's safe to take these medications while breastfeeding.
  - **Be instructed on the dangers of acetaminophen overdose.** Prescription pain medications that contain acetaminophen (e.g., Percocet®, Norco®) should **never** be taken with other products containing acetaminophen. Acetaminophen is found in many medications purchased over the counter. Taking too much acetaminophen can cause an overdose. Serious complications resulting from acetaminophen overdose can include abdominal pain, vomiting, and liver failure.

RESOURCES

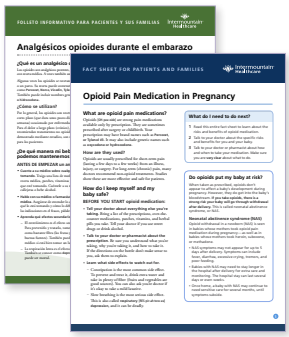
Patient resources

Breastfeeding and opioid pain medication

The *Breastfeeding and Opioid Pain Medication* handout will help your patients understand how to breastfeed if they must take opioid medicine for a short time. It is available in both *English* and *Spanish*.

Opioid pain medication in Pregnancy

The *Opioid Pain Medicine in Pregnancy* handout will help your patients understand when it might be necessary to use opioid medicines during pregnancy and how they can affect the baby. It is available in both *English* and *Spanish*.



Safe disposal of leftover medications

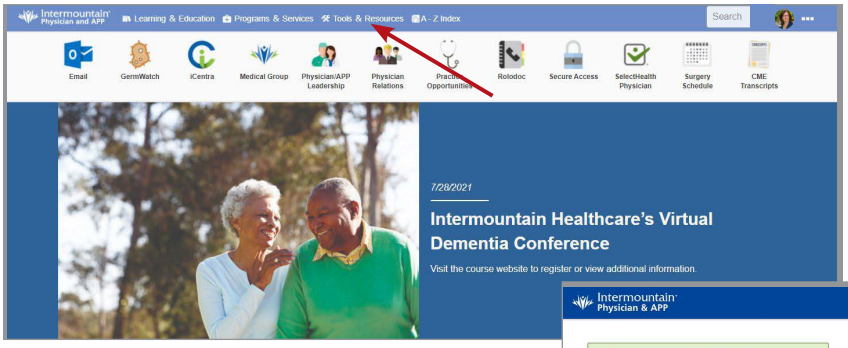
Leftover Medications: How to dispose of them safely, available in both *English* and *Spanish*.

Where to find or order

Intermountain approved patient education can be downloaded from the Patient Education Library (PEL) on Intermountain.net (idap access only). Additionally, clinicians and their patients can download education from Intermountain.org. Hard copies of approved Intermountain patient education booklets, fact sheets, and trackers can be ordered from Print It.

Provider resources

To find this and other CPMs, go to Phy.Intermountain.net (must log in with your idap) or Intermountainphysician.org.
Select **Care Process Models** from the **Tools and Resources** menu on the navigation bar at the top (or the menu on the left).



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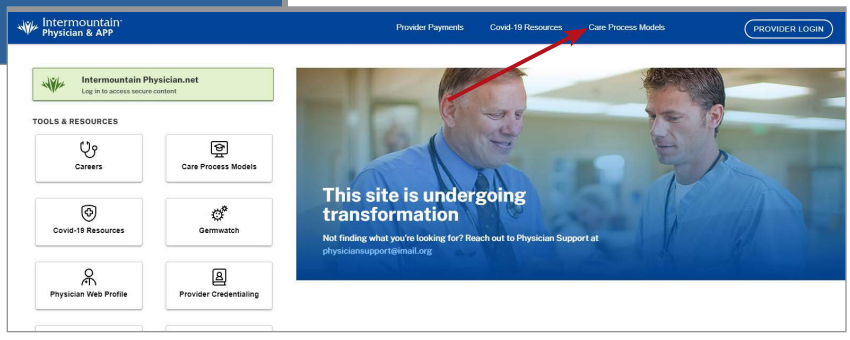

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This CPM presents a model of best care based on the best available scientific evidence at the time of publication. It is not a prescription for every physician or every patient, nor does it replace clinical judgment. All statements, protocols, and recommendations herein are viewed as transitory and iterative. Although physicians are encouraged to follow the CPM to help focus on and measure quality, deviations are a means for discovering improvements in patient care and expanding the knowledge base. Send feedback to Annette Crowley, Intermountain Healthcare, Clinical Programs Manager, Women's Health Clinical Program (**Annette.Crowley@imail.org**).