

Access Bridge

Addressing Today's Crisis in
Reproductive Health Access



Pharmacy and Therapeutics (P&T) Guidance

Getting Reproductive Health Medications on the Formulary

Providing the best treatment for your patients begins with access to all medication options. This process starts with your hospital's Pharmacy and Therapeutics (P&T) Committee.

[P&T Committees](#) oversee the hospital approval process for medication access and use. Typically, the committee includes pharmacists, hospitalists, specialists, quality improvement managers, and administrators.

Getting a Medication on Formulary 101

From the P&T Committee to Optimizing Medication Options for Your Clinical Practice Setting

1. Essential Preparation

- a. Build allies. Identify who needs to be on board, potential supporters, and detractors. Consider:
 - i. Pharmacist in charge of ED medications
 - ii. Pharmacist in charge of OBGYN medications
 - iii. Medical director/chair of OBGYN
 - iv. Director/chair of emergency medicine
 - v. Nursing director
- b. Ask for advice from the leaders listed above and from P&T members. People appreciate being asked for advice about how things work, who the key opinion-holders are, what types of evidence are most compelling, and what questions they would need answered to support the request.
- c. Meet with opinion-makers. Identify and address concerns preemptively before the meeting. Anticipate and address common misconceptions in your summary of evidence. Prepare talking points for commonly asked questions. Understand your detractors and their issues; prepare counter-arguments.
- d. Find other bright spots that can serve as examples and models.
 - i. Do other hospitals in the system or region already have mife/miso on formulary? Or do other highly respected hospitals in the state?
 - ii. If so, collect their monograph(s) and P&T packet—it is faster to edit than to create. Ask pharmacy and OBGYN for advice on how to modify documents to meet your hospital's P&T Committee standards.

2. P&T Committee Processes

- a. Each hospital has a system to add new medications to the formulary so providers can order them and nurses can administer them. The system can be managed at the local or regional level (if there is a network of facilities).
- b. Who is on the P&T Committee? Ask your local pharmacist supervisor about the members and current chair of the committee. Learn who they are!
- c. How does it work? Ask your pharmacist: When does the committee meet? How can you get your request on the agenda? What needs to be in the P&T packet? Ask for examples from past meetings.
- d. Get on the agenda. Email the committee chair. You can request a P&T champion to be assigned to you. Request all the forms you need to submit in advance.

3. SUBMIT PROPOSAL: Three Elements of a Successful P&T Request

- a. Describe P&T request
 - i. Goal: Add medication to hospital/ED formulary (e.g. mifepristone, misoprostol, contraceptives, and/or emergency contraceptives).
 - ii. Essential Information: Include, with evidence:
 - 1. Improves patient care. Effective, standard of care, safe.
 - 2. Low financial cost to the system: costs per medication administered, anticipated doses per month. Note that mifepristone is about \$43 per pill, one pill per treatment episode; misoprostol is less than \$1 per pill, and each patient requires 8-12 pills. Much cheaper than other commonly used drugs. Neither drug requires refrigeration or cold storage.
 - 3. Reasonable pharmacy processes:
 - a. For mifepristone: Explain the minimum necessary elements of the Risk Evaluation and Mitigation Strategies (REMS) (see [Appendix 1](#)):
 - i. Simple one-page form for pharmacy and prescribers (one prescriber can represent a larger group).
 - ii. One-page patient agreement: must be signed by every patient—the word “abortion” is not mentioned in the document.
 - iii. While mife/miso for miscarriage management is an off-label indication, it is still subject to the REMS requirements.
 - b. For emergency contraception (EC): Explain that neither medication option is an abortifacient. You can use the EC one-pager for support (see [Appendix 2](#)).
 - c. None of the reproductive health medications are controlled substances; none require refrigeration or special storage.
- b. Summary of Evidence (see resources in [Appendix 2](#))
 - i. Patient care data: review standard of care, safety, ACOG references.
 - ii. Financial and ED flow data: reduces bouncebacks, advantages for ED throughput, better stewardship of consultant resources.
- c. Conflict of Interest Statement (no financial gain from request)

Optimizing medication options, once mifepristone is on formulary.

Is Mifepristone available in your clinical practice setting?

1. Information about Mife REMS

- a. Know the [updated FDA REMS requirements](#); know that mifepristone is under litigation, and these REMS requirements may be lifted entirely or may be reversed to earlier FDA requirements.
- b. Know which *brand* of mifepristone is carried in your facility: Danco or GenBioPro. Each has separate branded one-page certification forms (for the pharmacy and prescribers) and patient forms (consent and medication guide).
 - i. GenBioPro
 1. [Prescriber agreement form](#)
 2. [Pharmacy agreement form](#)
 3. [GenBioPro patient agreement](#)
 4. [GenBioPro medication guide](#)
 5. [GenBioPro medication guide, see “Need Translated Documents” under medication guide section](#)
 - ii. Danco
 1. [Prescriber agreement form](#)
 2. [Pharmacy agreement form](#)
 3. [Danco patient agreement](#) (see [HERE](#) for other languages)
 4. [Danco medication guide](#)
 5. [Danco medication guide](#) (see [HERE](#) for other languages)
- c. Prescriber certification
 - i. Mifepristone must be ordered by a health care provider certified under the Mifepristone REMS Program. Options include:
 1. All ED prescribers complete the form.
 2. One prescriber completes the form on behalf of the ED medical group and all residents (for training programs), or on behalf of the ED medical providers (physicians and advanced practice clinicians, for hospitals without residency training programs). In this case, any prescriber in the ED is operating under the supervision of that prescriber, for the purpose of the REMS program.
 3. The emergency department can set an expectation to complete the REMS certification form as an opt-out or opt-in process.
 4. If not all providers are certified, and there is no supervising prescriber, create a system so clinicians, nurses, and staff know who can order mifepristone (posted on the wall, accessible electronically, or highlight/asterisk on electronic scheduling or tracking systems).
- d. Patient Agreement Form: Use the manufacturer-specific forms linked above. The **patient medication guides** (linked above) *are also* manufacturer-specific and must be provided to each patient.
 - i. The Patient Agreement Form is not designed for miscarriage management. It contains outdated information that may not be clinically relevant. Tips for explaining inconsistencies to patients:
 1. Mifepristone: Federal rules require all patients to sign this form, even though the form is not designed for miscarriage. It talks about “ending a pregnancy.” In

the case of miscarriage, the pregnancy has already ended but not completely expelled. The medications help your body finish the miscarriage in a shorter period of time.

2. Mifepristone and misoprostol used together are the medications proven to work best for miscarriage and are recommended by the country's professional association of OBGYNs, the American College of Obstetricians and Gynecologists.
 3. Miscarriage management is not an FDA-approved indication, but medications are commonly used off-label. [About 1 in 5 commonly used medications](#) are not FDA-approved, even when they are the best for a particular condition – like morphine and aspirin.
 4. Follow-up is optional. Studies show that follow-up is unnecessary if you feel fine and the medicines work. Here's how to know:
 - a. (If missed ab) The medications worked if you have 1) bleeding like a heavy period, 2) your pregnancy symptoms go away within a week, and 3) your home pregnancy test is negative in 5 weeks. In that case, you do not need an ultrasound or blood test for follow-up. If you don't have all three of these signs/conditions, you should see a provider for follow-up.
 - b. (If miscarrying and already bleeding): The medications worked if: 1) the bleeding slows down, 2) pregnancy symptoms go away within a week, and 3) your home pregnancy test is negative in 5 weeks. If all of those are true, you do not need an ultrasound or blood test for follow-up. If you don't have all three of these signs/conditions, you should see a provider for follow-up.
- ii. EDs manage the documentation requirements in various ways:
1. An EHR miscarriage template can include the SOAP note and required patient agreement, which is signed electronically by the patient, or signed on paper and scanned into the chart.
 2. Brand-specific Patient Medication Guides can be added to EMR and printed as a part of discharge education materials or handed directly to patients.

Need help? Both Danco and GenBioPro have great reputations for guiding clinicians through the process. 340B prices may be available.

- *Danco*, \$43 per pill
 - Distributor: AmerisourceBergen
 - Contact: Abby Long, Email: along@earlyoptionpill.com
- *GenBioPro*, \$42.50 per pill
 - Distributor: RS Northeast
 - Contact: Taylor McDowell, Email: support@genbiopro.com

Appendix 2: Resources for P&T Proposal

For Mifepristone

1. [Mifepristone REMS Guidance Sheet](#)
2. [Medication Management of EPL Factsheet](#)
3. [EPL References](#)

For EC

1. [EC One Pager](#)

Note: P&T sample package will be added at future date

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