

Protocol for Medication Management of Early Pregnancy Loss:

Mifepristone & Misoprostol

Eligibility

Patients with a nonviable pregnancy up to 12 weeks gestational age are eligible for medication management.

Non-viable pregnancy is diagnosed by ultrasound criteria and/or falling quantitative hCG levels. Gestational age is based on ultrasound findings rather than last menstrual period (LMP). Ectopic pregnancy must be excluded, or patient may be managed as a pregnancy of unknown location.

Contraindications to medication management include hemodynamic instability, severe anemia or bleeding disorders, inherited porphyrias, allergy to mifepristone or misoprostol, or liver disease.

Procedure

1. **Labs:** Possible labs include Rh screen, hematocrit, and quantitative serum hCG level. Testing for Rh status can be considered if the patient's status is unknown, however the evidence supporting this practice is minimal. Based on current practice guidelines, it is reasonable to forgo this testing up to 12 weeks, however institutional policies may vary. A baseline hemoglobin or hematocrit level can be obtained, especially if there is a history of anemia, but it is not required. Serum hCG level may be deferred in patients who can follow-up with ultrasound, if the initial diagnosis was made by ultrasound.
2. **Counseling:** Clinically stable patients should be counseled on all options for managing early pregnancy loss including expectant, medical management, and uterine aspiration.
3. **Consent forms:** For patients who choose medical management with mifepristone and misoprostol, the patient and clinician must sign the [Distributor's mifepristone patient agreement form](#) (required by FDA). Consider signing an additional, [evidence-based consent form](#) explaining use of mifepristone for pregnancy loss rather than abortion.
4. **Mifepristone:** One tablet of mifepristone 200 mg should be dispensed in the office or prescribed to a pharmacy that carries it. The patient should be instructed to swallow the mifepristone at a convenient time and place. (It does not need to be swallowed in the office.) If dispensing mifepristone in-office, record the mifepristone NDC number in the medical record. If mifepristone is not available, the patient may begin the treatment with misoprostol alone.*

5. **Misoprostol:** Prescribe or dispense four tablets of 200 mcg misoprostol (800 mcg total) for the patient to use vaginally or buccally 24 hours following mifepristone. The patient places 800 mcg of misoprostol in the vagina or buccally. The patient should be instructed to lie down for 30 minutes following vaginal insertion of misoprostol. Consider prescribing a second dose of 800 mcg of misoprostol in case heavy bleeding does not occur within 12-24 hours of the first dose.
6. **Supportive medications:** A prescription for a non-steroidal anti-inflammatory medication, such as ibuprofen or naproxen, should be offered to the patient. Instruct the patient to take pain medication prior to misoprostol insertion, and then as needed for pain. Offering anti-emetics, such as ondansetron or meclizine, may also be considered.
7. **Patient Instructions** (see [RHAP take home instructions](#) to give to patient):
The patient should be given contact information for how to reach their provider and be provided with guidelines regarding when to call. Patients should be instructed to call for:
 - a. Heavy bleeding, defined as soaking through two thick maxi pads per hour for 2 hours in a row;
 - b. Fever or purulent vaginal discharge; or
 - c. Uncontrolled pelvic cramps or pain not improved with medication.

The patient does not need to bring products of conception back to the clinician.

8. **Follow up:** Patients should schedule follow-up to ensure a complete passage of tissue in one of two ways: 1) repeat quantitative serum hCG level following passage of tissue (a drop of 80% by 7 days) or 2) a transvaginal ultrasound with absence of sac. Note: if one of these criteria has been met, no further follow-up of serum hCGs is warranted.

If no passage of tissue occurs (the patient has not bled as much as a period) within 12-24 hours of taking the misoprostol, the patient may use a second dose of 800 mcg misoprostol. If no passage of tissue occurs by 48 hours, the patient may resume expectant management or be referred for uterine aspiration.

9. **Documentation:** A chart note must be completed, to document the above and ensure a follow-up plan.

*If mifepristone is not available, misoprostol alone can be used, with a success rate of 67% by 2 days and 89% by 8 days .

References

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