

## Mifepristone/misoprostol abortion protocol

The FDA updated its labeling for mifepristone on March 29, 2016. The new label incorporates most recent evidence, allowing us to provide medication abortion in a way that minimizes adverse effects while enhancing safety, privacy, and convenience for patients and providers.

The new FDA label has made the following updates:

- The maximum **gestational age is 70 days**.
- The **mifepristone dosage is 200 milligrams** (one pill). The new label states that the mifepristone must be **“dispensed” in the office** but does not specify where the pill should be taken – which allows option for home administration.
- **Mucosal misoprostol administration** has increased efficacy and minimizes gastrointestinal side effects and is now specified over the prior oral administration. The FDA label recommends misoprostol 800 mcg buccally from 24-48 hours after mifepristone. An alternate evidence-based route is vaginal misoprostol administration, allowing a window of 6-72 hours after mifepristone. NOTE: For gestational ages under 5 weeks and over 8 weeks, optimal misoprostol timing is 24 hours for either buccal or vaginal routes.
- **Home use of misoprostol** is now recommended.
- Follow-up occurs 7-14 days after mifepristone, and **and location is flexible**, allowing for follow-up via phone, email, patient portal, etc.
- The **prescriber can be any prescribing clinician**, including advanced practice clinicians.

Protocol Comparison Table

	FDA regimen 2016 Buccal Misoprostol	Alternative: Vaginal misoprostol
Maximum gestational age	70 days from LMP	70 days from LMP
Mifepristone dose/location	200 mg. orally Dispensed in office	200 mg. orally
Misoprostol dose/route	800 mcg. Buccally (4 tablets)	800 mcg. Vaginally (4 tablets)
Misoprostol timing	24-48 hours after mifepristone *	6-72 hours after mifepristone *
Misoprostol location	Home	Home
Follow-up timing & location	7-14 days after mifepristone, location not specified	7-14 days after mifepristone, location not specified
Minimum number of contacts	1-2 office visits	2 contacts (office visits, web visits, phone calls, or messages)

	FDA regimen 2016 Buccal Misoprostol	Alternative: Vaginal misoprostol
<b>Prescriber</b>	...By or under the supervision of a certified prescriber	...By or under the supervision of a certified prescriber
<b>Cost</b>	Lower	Lower

\* For gestational ages under 5 weeks and over 8 weeks, recommend 24 hour administration for any route.

## Patient Referral

If you accept medication abortion referrals from your partners or colleagues, the following paragraph may be helpful to them: The primary provider should counsel the patient about pregnancy options and contraception. Patients who choose medication abortion should receive an appointment with an appropriate provider as soon as possible. To avoid delays, a medication abortion provider should be contacted directly (by the primary provider or nursing staff) and a prompt appointment should be arranged.

## Initial Assessment – Office Visit - Day 1

### Counseling

1. Options counseling: Consider aspiration abortion or continuing the pregnancy and parenting or adoption. Advise that medication abortion has a failure rate (i.e. ongoing pregnancy) of about 1 in 250 and an aspiration abortion may be needed in 1 to 3 of 250 cases. Compared with aspiration abortion, medication abortion causes longer bleeding duration and more abdominal cramping. Medication abortion is non-invasive, avoids surgical and anesthetic risk, and can occur very early in pregnancy. It has been perceived by many patients to be more natural, and allows more privacy and control. (See consent form.)
2. Review of expected effects: Bleeding and cramping (usually heavier than with menses) are expected. Diarrhea and other gastrointestinal side effects are common. There is a very small risk of prolonged bleeding requiring an aspiration abortion or MVA. The patient should be instructed in how much bleeding would be considered excessive and when to call the clinician.
3. Adherence to protocol: Explain to the patient the process and the importance of finishing the medication abortion protocol. If the abortion is unsuccessful, an aspiration abortion or a repeat dosing of medications must be performed due to the possible teratogenicity of misoprostol.

## **Compliance with State Requirements**

Many states have specific requirements affecting abortion. Most of these laws apply both to medication and aspiration abortion. Providers must comply with mandatory waiting periods, parental notification, gestational age limits, and department of health reporting as required. To find out more about these regulations, consult

[www.reproductiverights.org/](http://www.reproductiverights.org/).

## **Medical History and Physical Exam**

1. Confirm pregnancy with a urine pregnancy test.
2. Rule out contraindications:
  - IUD in place (may be removed prior to medication abortion)
  - Allergy to prostaglandins or mifepristone
  - Chronic adrenal failure
  - Long-term systemic corticosteroid therapy
  - Ectopic pregnancy
  - Hemorrhagic disorders
  - Concurrent anticoagulant therapy (excluding aspirin)
3. Ensure that the patient has access to a telephone and transportation and agrees to return for follow-up appointments as needed.
4. Obtain a medical history. A bimanual exam can assist in gestational dating if the patient is not sure about last menstrual period.

## **Dating Pregnancy**

Ultrasound examination should be performed if gestational age is uncertain, if there is a size/date discrepancy, if sizing is difficult, if the patient's last menstrual period occurred while they were taking hormonal contraception, or if the clinician suspects ectopic pregnancy or if the LMP places them over 9 weeks. If none of these conditions warrant an ultrasound, a quant hCG should be done prior to the administration of the mifepristone and again at the follow-up visit to monitor the success of the abortion. The quant does not "date" the pregnancy, it allows for a comparison of the hCG levels before and after to assure a drop of > 80% at one week after the cramping and bleeding.

## **Quantitative bhCG, hemoglobin measurements obtained**

A quantitative bhCG level may be needed for comparison with a subsequent level. A baseline hemoglobin or hematocrit level can be ordered as well, especially if there is a history of anemia.

**Review the required provider/patient agreement** and the consent form.

**Give medication and directions for misoprostol administration:**

Buccal administration: The patient will administer four 200-microgram misoprostol tablets, holding two in each cheek for 30 minutes and then swallowing them with a drink, at a convenient time 24-48 hours after taking mifepristone.

Vaginal administration: The patient will place four 200-microgram misoprostol tablets in the vagina 6 – 72 hours after taking the mifepristone. The patient will then lie down for 30 minutes. If the tablets fall out after 30 minutes, they can be discarded.

If expulsion (i.e., cramping and bleeding) does not occur within 24 hours of the initial misoprostol dose, the patient should consult the clinician. A second dose of misoprostol or an ultrasound exam may be indicated.

**Advise patient on use of pain medications:** Prescriptions for acetaminophen with a narcotic and/or Ibuprofen 800 milligrams should be offered to the patient. Patients should be encouraged to fill the prescription/s in advance and to have the pain medications on hand to be taken as needed.

**Make sure patient knows how to reach clinician on-call.** An information sheet with instructions about how to call or page the provider should be given to each patient, and the information should be reviewed to be sure they understand. The patient should be instructed to call their clinician if they do not bleed within 24 hours of using the misoprostol, if bleeding exceeds two maxi-pads per hour for two consecutive hours, or if they begin to feel very ill at any time during the medication abortion process.

**Give mifepristone:** 200-milligram tablet by mouth, to be taken in office or later at home.

**Review plans for post-abortion contraception:** Patients who choose combination hormonal contraceptives (oral, patch, ring) may begin the method as soon as the next day or on the most convenient day after taking misoprostol – even if bleeding persists. The implant may be inserted the same day that the patient takes mifepristone. Depo progestin (Depo Provera) injection or IUD insertion can take place at the follow-up visit. Patients may begin to have vaginal sex with barrier contraception after 72 hours. Patients who choose tubal ligation should be referred as appropriate to avoid delays.

## Follow-up Assessment – Office or alternative – Day 7-14

### Follow-up to assess completeness of abortion

1. To assess the completeness of the abortion, clinicians should use the following criteria:
  - history (patient’s description of bleeding - which should be at least as much as their menses – with cramping and passage of clots);

- declining serum bhCG levels (by more than 80% at one week after the bleeding) or by negative urine pregnancy test (i.e. below minimum level) and/or ultrasound.
2. If pregnancy is ongoing, i.e. a rising bhCG or a sonogram with a growing pregnancy, an aspiration completion can be performed. If the abortion is incomplete (i.e. a sonogram showing no interval growth and no fetal heartbeat), the patient can choose a repeat dose of vaginal misoprostol or an aspiration procedure. If the pregnancy was being followed by quant hCGs and they did not fall as expected, an urgent ultrasound should be obtained to assess for failed abortion vs ectopic pregnancy.
  3. The contraception plan should be reviewed and confirmed.

### **Further follow-up**

Patients should be instructed to call or return if bleeding persists beyond 4 weeks or becomes heavy again.