Misoprostol-only Abortion Care Protocol

Misoprostol-only regimens for abortion care are endorsed as medically acceptable, safe and effective options by the World Health Organization, Society of Family Planning, National Abortion Federation, and other international and national professional guidelines for abortion care. Misoprostol-only regimens are recommended, particularly when mifepristone is not legally available or is inaccessible. This protocol provides directions on how to provide medication abortion care using misoprostol alone at or before 12 weeks of pregnancy. Misoprostol-only abortion care may also be appropriate after 12 weeks.

Protocol Summary for Medication Abortion with Misoprostol²

Maximum gestational age	84 days (12 weeks) from last menstrual
	period (LMP)
Misoprostol dose/route	800 mcg (4 tablets)
	Buccally, sublingually, or vaginally
	3-4 doses
Misoprostol timing	4 tablets every 3 hours for at least 3
	doses
Misoprostol location	Home
Follow-up	Offer follow-up. Ensure patients have a
	way to reach you for questions or
	concerns.
Prescriber	Any prescribing clinician, including
	advanced practice clinicians.*
Dispensing	In-person at clinic, via mail through
	clinic or mail-order pharmacy, or in-
	person at pharmacy.

^{*}In states that require abortions to be performed by a licensed physician, advanced practice clinicians cannot legally provide abortion care.⁵

Initial Assessment

⁵ Guttmacher Institute. Interactive Map: US Abortion Policies and Access After Roe. December 5, 2024. Accessed December 2024. https://states.guttmacher.org/policies/



¹ World Health Organization (WHO). Abortion care guideline. 2022. https://srhr.org/abortioncare/

² Raymond EG, Mark A, Grossman D, et al. Medication abortion with misoprostol-only: A sample protocol. *Contraception*. 2023;121:109998. doi:10.1016/j.contraception.2023.109998

³ National Abortion Federation. 2024 Clinical Policy Guidelines for Abortion Care. 2024. https://prochoice.org/providers/quality-standards/.

⁴ Baum S, Moseson H, Jayaweera R, Gerdts C. Misoprostol Only is Safe and Effective. Society of Family Planning. August 2023. https://societyfp.org/wp-content/uploads/2023/02/SFP_ScienceSays_misoprostol.pdf

Counseling

1. Options counseling: Assure that the patient understands options: continuing or ending the pregnancy. Advise that medication abortion with misoprostol alone successfully ends 82-100% of pregnancies without the need for procedural intervention. This range is wide due to different studies' variations in the timing of follow-up, evaluation for procedural intervention, misoprostol route, timing of doses, number of additional doses, and study participants' access to clinical care if needed. On average, 93% of patients will complete their abortion without additional intervention (additional doses of misoprostol, abortion procedure, etc.)

Patients may have more intense and prolonged side effects (fever, chills, diarrhea, nausea, cramping) when using misoprostol only for medication abortion compared to regimens using mifepristone and misoprostol. ^{7,8} 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. ⁹

- 2. Review of expected effects:
- Bleeding: The patient will have heavy bleeding and may see clots. Bleeding may begin within 1 to 4 hours after the first dose of misoprostol. The heaviest bleeding (usually heavier than menses) usually starts after the 3rd dose and will last 1-3 days. ¹⁰ Bleeding can last 2 weeks or sometimes longer. ⁸ The amount and duration of bleeding is likely to increase with gestational age. There is a very small risk of prolonged bleeding requiring uterine aspiration.
- The patient should be instructed in how much bleeding would be considered excessive (e.g. patient is soaking through more than 2 pads per hour for 2 hours in a row) and when to call the clinician (see below).
- Most people will notice expulsion of the products of conception within 24 hours of taking the first dose of misoprostol. The size of the pregnancy tissue increases with gestational age. You can use these pictures to help prepare patients for what they can expect to see based on their gestational age.

¹⁰ Ibis Reproductive Health. Experiences with misoprostol-only for medication abortion: Considerations when counseling patients on misoprostol-only. October 2023. https://www.ibisreproductivehealth.org/publications/experiences-misoprostol-only-medication-abortion-considerations-when-counseling.



⁶ Moseson H, Jayaweera R, Baum SE, Gerdts C. How Effective Is Misoprostol Alone for Medication Abortion?. NEJM Evid. 2024;3(6):EVIDccon2300129. doi:10.1056/EVIDccon2300129.

⁷ Ngoc NT, Blum J, Raghavan S, Nga NT, Dabash R, Diop A, et al. Comparing two early medical abortion regimens: mifepristone+misoprostol vs. misoprostol alone. Contraception 2011;83:410–7. https://doi.org/10.1016/j.contraception.2010.09.002.

⁸ Raymond et al., 2023.

⁹ Winikoff B. Acceptability of medical abortion in early pregnancy. Family Planning Perspectives. 1995;27:142-148. https://www.guttmacher.org/journals/psrh/1995/07/acceptability-medical-abortion-early-pregnancy.

- Cramping and uterine pain: Cramping is expected for up to a few days.
- There are other commonly reported side effects, that should not last longer than 24 hours after taking the last dose of misoprostol. If these last longer, patient should be instructed to contact the office to determine if they should seek care.
 - These include: diarrhea, nausea, vomiting, weakness, fever/chills, headache, and dizziness
- Other reasons patients could contact the office:
 - Severe or increasing pain or cramps that don't get better with pain medicine, rest, or heating pads
 - o Fever of 100.4°F or higher for more than 24 hours after last dose of misoprostol
 - o Bleeding that soaks through 2 maxi pads an hour for 2 hours or more
 - o Symptoms of allergic reaction (rash, shortness of breath)
 - Any concerns or questions
- One week after taking misoprostol, the patient should contact the office if they have any of the following symptoms of a possible continuing pregnancy:
 - o Light or no bleeding
 - Do not feel that they passed the pregnancy
 - o Pregnancy symptoms (nausea, breast/chest tenderness) are not resolving

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 dose is recommended.

Compliance with State Requirements

Many states have specific requirements affecting abortion. Most of these laws apply both to medication and aspiration abortion. Clinicians 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 the <u>Center for Reproductive Rights</u> or the Abortion Defense Network.

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 misoprostol
- Chronic adrenal failure
- Unilateral pelvic pain or significant bilateral pelvic pain within past week (could be sign of ectopic pregnancy)



- Ectopic pregnancy
- Hemorrhagic disorders
- Concurrent anticoagulant therapy (excluding aspirin)
- 3. Patients should have instructions for contacting the office for questions/concerns.
- 4. Obtain a medical history. A bimanual exam can assist in gestational dating if the patient is not sure about their last menstrual period.

Dating Pregnancy

Ultrasound examination should be performed if gestational age is uncertain, if there is a size/date discrepancy, if the patient's last menstrual period occurred while they were taking hormonal contraception, if the patient has a history of irregular menses, if the clinician suspects ectopic pregnancy, or if the LMP places them over 84 days (12 weeks). 11,12 If none of these conditions warrant an ultrasound, a quantitative hCG may be done prior to the administration of the mifepristone and again at a follow-up visit to monitor the success of the abortion. The hCG level 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.

Laboratory studies

A quantitative hCG level may be needed as above. A baseline hemoglobin or hematocrit level can be obtained, especially if there is a history of anemia. 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 prior to medication abortion before 12 weeks of gestation, however institutional policies may vary and it is important to be familiar with the standards for your practice setting.^{13,14}

5. Review the consent form.

Give medication (or prescription for pharmacy) and directions for misoprostol administration:

Provide 3-4 doses of misoprostol 800 mcg per clinician judgement taking into account the patient's specific situation. An additional dose should be provided that the patient can use if needed. Each dose of misoprostol is 800 mcg (four pills of 200 mcg each pill).

¹⁴ Horvath S, Goyal V, Traxler S, Prager S. Society of Family Planning committee consensus on Rh testing in early pregnancy. Contraception 2022;114:1–5. https://doi.org/10.1016/j.contraception.2022.07.002.



¹¹ Schonberg D, Wang LF, Bennett AH, Gold M, Jackson E. The accuracy of using last menstrual period to determine gestational age for first trimester medication abortion: a systematic review. Contraception 2014;90:480–7.

¹² Raymond EG, Grossman D, Mark A, et al. Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond. Contraception. 2020;101:361-366. doi:10.1016/j.contraception.2020.04.005

¹³ Mark A, Foster AM, Grossman D, Prager SW, Reeves M, Velasquez CV, et al. Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception 2019;99:265–6. https://doi.org/10. 1016/j.contraception.2019.02.008

The patient may choose to take the pills either of two ways:

<u>Buccal/sublingual administration:</u> The patient will hold two misoprostol pills in each cheek or four misoprostol pills under their tongue for 30 minutes, and then swallow any remaining fragments.

<u>Vaginal administration:</u> The patient will lie down and insert four misoprostol pills in the vagina. They should stay lying down for 30 minutes. If the pills fall out after 30 minutes, it's okay they can be discarded. If your patient is concerned about privacy, you can counsel them to put the pills inside their cheeks or under their tongue. This way, there will be no pill fragments left behind.

Patients should take one dose of 4 pills every 3 hours until they have taken 3 or 4 doses total. Patients can use either route for each dose. They should be instructed to keep taking the medication as directed, even if they are bleeding or having pain or other symptoms.

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

Advise patients in hostile environments: Patients in hostile environments (i.e. anti-abortion states, near Catholic hospitals, etc.) or who are concerned about privacy should consider using misoprostol buccally or sublingually to avoid having pill fragments in the vagina in the rare instance that they need an in-person follow-up exam.

Advise patient on use of supportive medications: Nonsteroidal anti-inflammatory drugs (NSAIDs) can be used 30 minutes before the first dose of misoprostol to manage uterine pain. Prescriptions for ibuprofen 800 mg and/or acetaminophen should be offered to the patient. Offering anti-emetics, such as ondansetron or meclizine, may also be considered. Patients should be encouraged to fill the prescription/s in advance and to have the medications on hand to be taken as needed. 15,16

Make sure the patient knows how to reach the clinician on-call: An information sheet with instructions about how to reach the clinician should be reviewed with each patient. The patient should be instructed to call their clinician if they do not bleed within 24 hours of using the

¹⁵ Committee on Practice Bulletins-Gynecology, Society of Family Planning. Medication Abortion up to 70 Days of Gestation. American College of Obstetricians and Gynecologists Practice Bulletin. 2020(225). https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation ¹⁶ National Abortion Federation. 2024.



January 2025 / www.reproductiveaccess.org

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.

Offer post-abortion contraception, if desired: Patients who choose the implant, progestin injection (Depo Provera), progestin-only pill, combined pill, or patch may start as soon as they take the first misoprostol dose. Patients can insert the ring within a few days after using misoprostol, after the heaviest cramping and bleeding. If patients start these methods later, they should be instructed to use a back-up method, like condoms. IUD insertion can take place as soon as early as four days after the last dose of misoprostol. Patients may begin to have vaginal sex with barrier contraception when they feel comfortable. Patients who choose a permanent method should be referred as appropriate to avoid delays.

Follow-up is optional.

- 1. To assess the completeness of the abortion, clinicians may use any of 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 accompanied by resolution of any pregnancy symptoms) via in-clinic or telemedicine encounter 1 week after misoprostol; or
 - declining serum hCG levels (by more than 80% at one week after the bleeding); or
 - ultrasound or pelvic exam; or
 - negative home pregnancy test 4 weeks after misoprostol. 17,18,19,20
- 2. If an at-home pregnancy test is still positive after 4 weeks after taking misoprostol, a repeat pregnancy test should be performed in office. If pregnancy is ongoing, i.e. a rising serum hCG or an ultrasound with a growing pregnancy, an aspiration procedure can be performed. If the abortion is incomplete (i.e. an ultrasound showing no interval growth and no fetal cardiac activity, but with retained tissue and continued bleeding), the patient can choose a repeat dose of misoprostol or an aspiration procedure. If the pregnancy was being followed by quantitative hCGs and levels did not fall as expected, an urgent ultrasound should be obtained to assess for failed abortion vs ectopic pregnancy.

²⁰ Baiju N, Acharya G, D'Antonio F, Berg RC. Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: a systematic review and meta-analysis. BJOG 2019;126:1536–44.



¹⁷ Perriera LK, Reeves MF, Chen BA, Hohmann HL, Hayes J, Creinin MD. Feasibility of telephone follow-up after medical abortion. Contraception. 2010;81(2):143-9.

¹⁸ Chen MJ, Rounds KC, Creinin MD, Casino C, Hou MY. Comparing office and telephone follow-up after medical abortion. Contraception. 2016;94(2):122-126.

¹⁹ WHO, 2022.