Telehealth Care for Medication Abortion Protocol: Mifepristone & Misoprostol

Overview (of the evidence, states may have tighter restrictions)

- Telehealth medication abortion is highly safe and effective.¹
- The maximum gestational age is 84 days from last menstrual period (LMP).²
- The mifepristone dosage is 200 milligrams (one pill). The FDA label allows clinicians and certified pharmacies to dispense mifepristone in-person or by mail. Find out whether your local pharmacy dispenses mifepristone here.
- FDA patient agreement forms can be sent and signed through secure email or text communications.
- Misoprostol (800 mcg) can be taken buccally, sublingually, or vaginally. Patients should insert misoprostol 24-48 hours after taking mifepristone. For patients with gestational age of 9 to 12 weeks, a second dose of misoprostol should be given for use 4 hours after the first.
- Patients in hostile environments 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 exam.
- Follow-up is optional. Patients should have instructions for contacting a clinician for questions/concerns. The urine pregnancy test to assure completion is done after 4 weeks and a communication from the patient that it was negative is ideal.
- The prescriber can be any prescribing clinician, including advanced practice clinicians.

Telehealth Care for Medication Abortion Process

The clinician should counsel the patient by phone or video chat about pregnancy options (and contraception if desired). Patients who choose medication abortion can then be counseled about the process. Patient information sheets can be emailed, faxed, or sent through patient portals.

Initial Assessment - Discussion of Home Medication Abortion

Counseling

1. Options counseling: Assure that the patient understands options: continuing or ending the pregnancy. Options for ending the pregnancy include medication and aspiration abortion.

2. Review of expected effects:

² National Abortion Federation. NAF's 2024 Clinical Policy Guidelines for Abortion Care. National Abortion Federation; 2024. https://prochoice.org/providers/quality-standards/



¹ Upadhyay, U.D., Koenig, L.R., Meckstroth, K. *et al.* Effectiveness and safety of telehealth medication abortion in the USA. *Nat Med* 30, 1191–1198 (2024). https://doi.org/10.1038/s41591-024-02834-w.

- Bleeding: The heaviest bleeding (usually heavier than with menses) will likely occur several hours after taking misoprostol and will last 1-2 days. Bleeding/spotting is typical up to 9-16 days.^{3,4} A small number of patients (8%) may experience some type of bleeding for 20 days or more.⁵ 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 (more than 2 soaked pads per hour for two hours in a row) and when to call the clinician (see below). The size of the pregnancy tissue increases with gestational age. You can use these pictures to help prepare patients for what they should expect to see based on their gestational age.
- Cramping and uterine pain is expected for up to a few days.³
- There are other commonly reported side effects, that should not last longer than 24 hours after taking 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 should 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
 - o 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 repeat dosing of medications is recommended.

Compliance with State Requirements

Many states have specific requirements affecting abortion. Most of these laws apply both to medication and aspiration abortion. Some states prohibit telehealth for abortion and mailing

⁵ U.S Food and Drug Administration. MIFEPREX (Mifepristone) Tablets Label. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf. Revised March 2016. Accessed December 2024.



³ 7 Ngo, T. D., M. H. Park, H. Shakur, and C. Free. 2011. Comparative effectiveness, safety and acceptability of medical abortion at home and in a clinic: A systematic review. Bulletin of the World Health Organization 89(5):360–370.

⁴ National Academies of Sciences, Engineering, and Medicine. 2018. The Safety and Quality of Abortion Care in the United States. Washington, DC: The National Academies Press. https://doi.org/10.17226/24950.

the pills.⁶ Some states have Shield Laws protecting clinicians who provide telehealth abortion to states with bans or restrictions. Providers must comply with mandatory waiting periods, parental notification, gestational age limits, and department of health reporting as required. To find out more about regulations in your state, visit the <u>Guttmacher Institute's website</u>. For a map of state policies impacting the provision of telehealth abortion, <u>visit RHITES' website</u>.

Medical History

- 1. Confirm that the patient has had a positive urine pregnancy test.
- 2. Rule out contraindications:
 - IUD in place (may be removed by patient⁷ or clinician prior to abortion)
 - Allergy to prostaglandins or mifepristone
 - Chronic adrenal failure
 - Long-term systemic corticosteroid therapy
 - Hemorrhagic disorders
 - Ectopic pregnancy
 - Concurrent anticoagulant therapy (excluding aspirin, which is OK)
- 3. Patients should have instructions for contacting a clinician for questions/concerns.
- 4. Obtain LMP. If patient is uncertain about LMP, has irregular menstrual cycles, or clinician is concerned about ectopic pregnancy (risk factors include history of previous ectopic pregnancy, vaginal bleeding since LMP, adnexal pain, IUD in place, history of tubal surgery, and history of treatment for PID), an ultrasound will need to be obtained. Ultrasound examination should also be performed if the LMP places the pregnancy at >12 weeks (84 days). If ultrasound is not indicated, gestational dating should be done by LMP.^{8,9,10}
- 5. 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 84 days LMP. Institutional policies may vary and it is important to be familiar with the standards for your practice setting.²

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

¹⁰ Royal College of Obstetricians & Gynecologists. "Coronavirus (COVID-19) infection and abortion care." Version 1: published March 21, 2020.



 $^{^6}$ Guttmacher Institute. "Medication Abortion." (2022). https://www.guttmacher.org/state-policy/explore/medication-abortion

⁷ Foster, Diana Greene, et al. "Interest in and experience with IUD self-removal." *Contraception* 90.1 (2014): 54-59.

⁸ Bracken, H., et al. "Alternatives to routine ultrasound for eligibility assessment prior to early termination of pregnancy with mifepristone–misoprostol." BJOG: An International Journal of Obstetrics & Gynaecology 118.1 (2011): 17-23.

⁹ Raymond, Elizabeth G., et al. "Simplified medical abortion screening: a demonstration project." Contraception 97.4 (2018): 292-

This can be done electronically by securely emailing or texting the patient the required forms.

Determine if the patient would like the pills mailed or picked up in-clinic or at a certified pharmacy.

If mailing is an option: the mifepristone 200-mg tablet and 4 to 8 200 mcg tablets (1-2 doses) of misoprostol should be put into envelopes and mailed to the patient's home or preferred address. If possible, a urine pregnancy test for the patient to assess abortion completion should be mailed as well, with the aftercare instructions and a copy of the consent form.

Give directions for misoprostol administration:

<u>Buccal administration:</u> The patient will hold two misoprostol pills in each cheek or four misoprostol pills under their tongue for 30 minutes, then swallow any remaining fragments with a drink, at a convenient time 24-48 hours after taking mifepristone.¹¹

<u>Vaginal administration</u>: The patient will lie down and insert four misoprostol pills 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.¹²

If gestational age is 63-84 days, a second dose of misoprostol is recommended to increase efficacy. This should be taken four hours after the first dose of misoprostol.

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.¹³



¹¹ Chen, Melissa J., and Mitchell D. Creinin. "Mifepristone with buccal misoprostol for medical abortion: a systematic review." *Obstetrics & Gynecology* 126.1 (2015): 12-21.

¹² Schaff EA, Fielding SL, Westhoff C, Ellertson C, Eisinger SH, Stadalius LS, et al. Vaginal misoprostol administered 1, 2, or 3 days after mifepristone for early medical abortion: A randomized trial. JAMA 2000;284:1948-53.

¹³ National Abortion Federation, 2024.

Make sure the patient knows how to reach the clinician on-call.

An information sheet with instructions about how to call the clinician or office should be sent to each patient, and the information should be reviewed during the counseling to be sure they understand.

Follow-up is optional.

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); or
- declining serum bhCG levels (by more than 80% at one week after the bleeding); or
- ultrasound; or
- negative home pregnancy test 4 weeks after mifepristone. 14,15

If an at-home pregnancy test is still positive after 4 weeks after taking mifepristone, a repeat pregnancy test should be performed in office. If pregnancy is ongoing, i.e. a rising bhCG 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 quant hCGs and levels did not fall as expected, an urgent ultrasound should be obtained to assess for failed abortion vs ectopic pregnancy. Patients should be instructed to call or come into the office if bleeding persists beyond 4 weeks or becomes heavy again.

Offer post-abortion contraception, if desired:

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 safely inserted the same day that the patient takes mifepristone, if an appointment is available for them. However, implant or IUD insertion can take place at a follow-up visit and a bridge method can be used until that time. The progestin injection (Depo Provera) on the same day that patient takes mifepristone may somewhat decrease the effectiveness of the medication abortion, but can safely be initiated on the day of mifepristone or at a follow-up visit, depending on patient preference. Same day progestin injection is

¹⁵ 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.



¹⁴ 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.

associated with increased ongoing pregnancy rate compared to initiation at follow-up (3.6% vs 0.9%), but patient satisfaction is higher. 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.

¹⁶ Raymond EG, Weaver MA, Louie KS, et al. Effects of Depot Medroxyprogesterone Acetate Injection Timing on Medical Abortion Efficacy and Repeat Pregnancy: A Randomized Controlled Trial. Obstet Gynecol. 2016;128(4):739-745. doi:10.1097/AOG.000000000001627

