

**Penn Family Care  
MEDICAL ABORTION GUIDELINES**

**I. Mifepristone and Misoprostol**

**A. Eligibility**

1. Contraindications:
  - a. Hemorrhagic disorder or concurrent anticoagulant therapy;
  - b. Chronic adrenal failure;
  - c. Concurrent long-term systemic corticosteroid therapy;
  - d. Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass or tenderness;
  - e. Inherited porphyrias;
  - f. IUD in place (must remove before treatment);
  - g. History of allergy to mifepristone, misoprostol or other prostaglandin;
  - h. Unwillingness to undergo a surgical abortion (if indicated);
  - i. Hematocrit less than 34%;
2. Intrauterine pregnancy no more than 63 days from the first day of the last menstrual period (LMP), confirmed by transvaginal ultrasound;
3. Is able to give informed consent and comply with treatment requirements, receive the mifepristone/Mifeprex™ Medication Guide, and sign the mifepristone/Mifeprex™ Patient Agreement; and
4. Has access to a telephone and transportation to a medical facility equipped to provide emergency treatment of incomplete abortion, blood transfusions, and emergency resuscitation.
5. Special considerations:
  - a. Patient should have no degree of ambivalence with decision.
  - b. Patient should not be breastfeeding from the time of the procedure to three days following the use of misoprostol as data is not available on effects of mifepristone or misoprostol while breastfeeding.
  - c. Other conditions that may contraindicate mifepristone and/or misoprostol use and require individual evaluation by physician to determine the safest method of pregnancy termination include:
    - i. History of anemia
    - ii. Poorly controlled bowel disease or concurrent illness with significant diarrhea
    - iii. Serious systemic illness (e.g. severe liver disease, significant cardiac disease, renal failure, uncontrolled seizure disorder)
  - d. Household member must know of pregnancy and medical abortion.
  - e. Patient must exhibit level of maturity to ensure compliance with treatment instructions.
  - f. Patient should speak, read, and write English or have 24-hour access to bilingual translator.

**B. Counseling, Education, and Informed Consent**

1. Each patient will be counseled about abortion options available at the time of their initial request for abortion services by her primary care physician. The discussion will include advantages and benefits, disadvantages and risks, visit schedule, fees, and medical assessment for contraindications.
2. If the patient meets the criteria and she wishes to receive medical abortion services at Penn Family Care, the information required by the Pennsylvania Abortion Control Act will be discussed. This will occur at least 24 hours before the abortion itself is initiated.
3. At the medical visit (Day One), the physician will review:
  - a. The decision to have an abortion and assurance that the decision is the patient's own with no degree of ambivalence;
  - b. Non-surgical and surgical alternatives and the risks and benefits of each;
  - c. Known side effects and possible complications of mifepristone and misoprostol, including:
    - i. If pregnancy is not fully expelled from the uterus, it could cause infection or other complications;
    - ii. Mifepristone is not known to increase the risk of teratogenesis in humans, but that fetal malformations have been reported after first trimester use of misoprostol. Patient must be strongly advised to complete the abortion, either medically or surgically, once the medications have been administered;
    - iii. Information about what symptoms warrant contacting the on-call provider, for example:
      - a. soaking 2 or more maxipads per hour for 2 consecutive hours;
      - b. sustained fever or onset of fever days after misoprostol;
      - c. no bleeding within 24 hours after using misoprostol, as this may indicate an ectopic pregnancy;
  - d. Explanation that mifepristone combined with misoprostol has been approved by the FDA for induction of abortion, but that our regimen differs from the FDA label;
  - e. The approximate amount of time involved, typically several days, and the possibility of multiple visits;
  - f. Pain experienced by previous patients and the use of pain medications. The patient should have an appropriate supply and instructions for use of oral pain medications once treatment is initiated. Pain is typically described as cramping and is most intense during expulsion, most commonly over a 1-3 hour period, after which the pain usually subsides;
  - g. Instruction concerning the administration of misoprostol;
  - h. The amount and quality of bleeding associated with the abortion process, including:
    - i. bleeding is typically heavier than menses and may depend on the length of the pregnancy;
    - ii. likelihood of the passage of clots;
    - iii. an embryo is approximately the size of a grain of rice at the time when medical abortion is most commonly provided, and is not typically seen until 8 ½ to 9 weeks gestation;
    - iv. while many women may start bleeding prior to misoprostol, misoprostol is typically needed to complete the process;
    - v. patients should use maxi-pads to allow the clinician to assess the amount of bleeding;
  - i. The Medication Guide, Patient Agreement, and Penn Family Care informed consent form. The physician will sign and print her/his name on the patient agreement where it says

- “Provider Signature” and give one copy to the patient and keep one copy in the chart. The Penn Family Care informed consent specifies any differentiations from the FDA regimen and details the evidence-based regimen being used;
- j. Issues regarding confidentiality;
  - k. Review of aftercare instructions and 24-hour emergency contact information; and
  - l. Contraception options available. Contraception may be started immediately after confirmation of a complete abortion.

### C. Medical History and Physical Examination

1. Review pertinent medical and obstetrical history, including history of allergies and all current patient medications;
2. Pertinent physical examination, including vital signs;
3. Transvaginal ultrasound for confirmation of gestational age and intrauterine gestation.

#### Ultrasound exam

An ultrasound examination should be performed on all patients unless the clinician assesses it is not needed. The name of the patient and the date of the examination must be noted on the sonogram. A copy of this sonogram must be kept in the chart.

If an intrauterine pregnancy is identified, the pregnancy will be dated by the following formulas:

EGA = 30 + size of gestational sac in mm; or

EGA = 42 + crown rump length of embryo if present.

The presence of a fetal heart beat and/or yolk sac is noted in the chart if present.

**A patient qualifies for a medical abortion with mifepristone if an intrauterine pregnancy is identified with a yolk sac and/or embryo, and the EGA is less than or equal to 63 days (CRL less than or equal to 21 mm). A medical abortion with mifepristone may also be completed if there is a gestational sac without a yolk sac and a BhCG of less than 2000.**

If there is no gestational sac is noted, or there is a gestational sac without a yolk sac on ultrasound, the patient may receive mifepristone if the LMP is less than 35 days and the adnexae are normal on physical examination and ultrasound. A BhCG must be drawn and followed on the next visit. Bleeding and a drop of BhCG by 50% confirm a successful abortion with mifepristone. If there is no bleeding, and/or a lesser drop in BhCG levels, an ectopic pregnancy must be ruled out.

If there is no gestational sac noted on the ultrasound, the date of the LMP was less than six weeks, and the adnexae appear normal on physical examination and ultrasound, the patient may be given the option of waiting for one week, or of using methotrexate. Mifepristone may be used if the BhCG is less than 2000. BhCG must be followed until it declines by 50% after the abortion.

4. Lab work
  - a. Documentation of Rh factor.

- b. Documentation of hematocrit.
- c. Urine hCG and  $\beta$ -hCG level are not required unless being used to monitor the completeness of the abortion or if ectopic pregnancy is suspected.
- d. Documentation of urinalysis for protein and glucose.
- e. Other tests as medically indicated.

#### **D. Medication Administration and Follow-Up**

1. Medication must be administered or supervised by a faculty physician trained to:
  - a. Assess the pregnancy's gestational age;
  - b. Diagnose ectopic pregnancies;
  - c. Provide surgical aspiration intervention or have plans in place to provide such care through others if needed; and
  - d. Assure patient access to emergency medical facilities equipped to provide blood transfusions and emergency resuscitation during the treatment procedure.
  
2. Medication administration:
  - a. Day one:
    - i. Mifepristone 200 mg (one 200 mg tablets) taken as a single oral dose. Evidence-based studies have shown this regimen to be as effective as the FDA-approved 600 mg regimen when used up to 63 days of pregnancy.
    - ii. Rh immune globulin for Rh-negative patients (must administer within 72 hours). For women having a medical abortion the 50- $\mu$ g dose is adequate.
    - iii. The recommended pain control regimen is 800 mg of Ibuprofen taken orally at the time of insertion of the vaginal misoprostol. If the patient continues to have severe cramps two hours after taking the ibuprofen, they may take two tablets of Tylenol #3, 440 mg of naprosyn, or up to 1000 mg of acetaminophen. Patients will be given a prescription of Tylenol #3, 6 tablets, when they leave the office. She will be instructed to call for a prescription for Tigan if she experiences severe nausea or vomiting.
    - iv. The patient is given 800- $\mu$ g misoprostol and instructed to insert the tablets vaginally or buccally at home on day 3 in the morning (approximately 48 hours later). Evidence based research has shown that patients using this regimen experience fewer gastrointestinal side effects, than with the FDA-approved 400- $\mu$ g regimen taken orally, and it increases the proportion of women with onset of bleeding and pregnancy expulsion within 4 hours of misoprostol administration.
  
3. Follow-up
  - a. Patient will be called by the physician between day 4 and day 10 to assess status.
  - b. Patient should return for a follow-up visit between days 10 - 14 to be assessed for completion of abortion.
  - c. The physician will assess the patient for pregnancy expulsion and confirm by transvaginal ultrasound under guidance of a faculty member trained and credentialed for this.

- d. If complete, the physician will review post-treatment instructions about bleeding, cramping, signs of incomplete abortion, contraception options and future care. If she is still pregnant, treatment options will be discussed.
- e. If a viable pregnancy is detected at this time, surgical termination is recommended because of the risk of fetal malformations if the pregnancy continues.
- f. Contraception of any type may be started immediately after confirmation of abortion.
  - i. Depo-Provera injections may be given at the follow-up.
  - ii. If oral contraceptives are ordered, the patient will be given a prescription for two refills and advised to have a yearly physical and pap smear in two to three months. Patient should begin taking oral contraceptives the Sunday following her follow-up exam.
- g. If a surgical abortion was necessary, the patient will schedule a post-surgical check-up two to three weeks afterwards to ensure there were no post-operative problems.
- h. The patient will be reminded that a physician will be on-call 24 hours a day for assessment of potential complications and emergencies.

## **II. Methotrexate and Misoprostol**

### **A. Eligibility**

1. Contraindications:
  - a. Hemorrhagic disorder or anticoagulant therapy;
  - b. Chronic adrenal failure;
  - c. Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass or tenderness;
  - d. IUD in place (must remove before treatment);
  - e. History of allergy or intolerance to methotrexate or misoprostol;
  - f. Irritable Bowel Syndrome (IBS) or poorly controlled bowel disease
  - g. Unwillingness to undergo a surgical abortion (if indicated);
  - h. Patients currently breastfeeding;
  - i. Hematocrit less than 30%;
  - j. Serious systemic illness including severe liver disease, significant cardiac disease, renal failure, and uncontrolled seizure disorder;
  - k. History of or current substance abuse;
2. Intrauterine pregnancy no more than 49 days from the first day of the last menstrual period (LMP), confirmed by transvaginal ultrasound;
3. Is able to give informed consent and comply with treatment requirements; and
4. Must have access to a telephone and transportation to a medical facility equipped to provide emergency treatment of incomplete abortion, blood transfusions, and emergency resuscitation.
5. Special considerations:
  - a. Patient should have no degree of ambivalence with decision.
  - b. Household member should know of pregnancy and medical abortion.
  - c. Patient should exhibit level of maturity to ensure compliance with treatment instructions.
  - d. Patient should speak, read, and write English or have 24-hour access to bilingual translator.

## **B. Counseling, Education, and Informed Consent**

1. Patient will be counseled about abortion options as described for Mifepristone.
2. If the patient meets criteria, she will discuss the following with her primary care physician at least 24-hours before the abortion:
  - a. Information required by the Abortion Control Act.
  - b. The decision to have an abortion and assurance that the decision is the patient's own with no degree of ambivalence;
  - c. Non-surgical and surgical alternatives and the risks and benefits of each;
  - d. Known side effects and possible complications of methotrexate and misoprostol, including:
    - i. If pregnancy is not fully expelled from the uterus, it could cause infection or other complications;
    - ii. That methotrexate and misoprostol have been shown to cause severe birth defects - if the procedure is not completed medically, it must be completed surgically.
  - e. Explanation that methotrexate combined with misoprostol has not been approved by the FDA for induction of abortion, and is being used "off-label";
  - f. The approximate amount of time involved and the possibility of multiple visits;
  - g. Pain experienced by patients and the use of pain medications;
  - h. Instruction concerning the administration of misoprostol;
  - i. The amount of bleeding to expect, size of clots and embryo, and the possibility of observing the embryo at home;
  - j. Contraception options available;
  - k. Review of the consent form;
  - l. Issues regarding confidentiality;
  - m. Review of aftercare instructions and emergency contact information.
3. At the medical visit, the patient will meet with a counselor to review above information and instructions, and answer any questions prior to methotrexate administration.

## **C. Medical History and Physical Examination**

1. Review pertinent medical and obstetrical history, including history of allergies and all current patient medications;
2. Transvaginal ultrasound
  - a. For confirmation of gestational age and intrauterine gestation.
  - b. Ultrasound exam (gestational sac, embryonic pole, presence of cardiac activity or yolk sac) must be documented in the medical chart before administering methotrexate.
  - c. If embryonic pole is visible, use this measurement instead of gestational sac measurement.
  - d. If intrauterine sac is not present, methotrexate should not be administered and patient should be evaluated to rule out ectopic pregnancy or miscarriage.
3. Lab work
  - a. Documentation of Rh factor.
  - b. Documentation of hematocrit.

- c. Urine hCG and  $\beta$ -hCG level are not required unless being used to monitor the completeness of the abortion or if ectopic pregnancy is suspected.
- d. Documentation of urinalysis for protein and glucose.
- e. Other tests as medically indicated.

4. Other tests as medically indicated.

#### **D. Medication Administration and Follow-Up**

1. Medication must be administered by or under the supervision of a faculty physician trained in abortion.
2. Medication administration:
  - a. Patient's height and weight will be measured and her body surface area calculated.
  - b. The correct dose of methotrexate will be calculated and  $50 \text{ mg/m}^2$  given as an IM injection.
  - c. Rh immune globulin for Rh-negative patients is administered after the methotrexate injection.
  - d. The patient will be given two sets of 800- $\mu\text{g}$  misoprostol each to take home and is instructed to insert the first set into her vagina 5-7 days following the injection. If she does not bleed significantly the day after insertion, she is instructed to insert the second set 24 hours later.
  - e. The patient will be given a prescription for Tylenol #3 for pain or if allergic to codeine, may be given a prescription for ibuprofen, darvocet, vioxx, or other pain medication determined by the physician. She will be instructed to call for a prescription for Tigan if she experiences severe nausea or vomiting.
  - f. The patient will be observed for allergic reactions to methotrexate for 20 minutes before being discharged from recovery.
3. Follow-up
  - a. Patient should be seen between 7 to 10 days after misoprostol insertion for follow-up.
  - b. The patient's physician will obtain patient history and assess patient's progress. She will review possibility of failure and contraception options again.
  - c. The physician, under the supervision of a trained faculty physician, will assess the patient for pregnancy expulsion and confirm by transvaginal ultrasound.
  - d. If abortion has not occurred, and cardiac activity is present, surgical termination is recommended because of the risk of fetal malformations. If sac is present and no development has occurred, patient has option of 2<sup>nd</sup> methotrexate and/or third set of misoprostol and returning for another follow-up exam in 5-7 days.
  - e. When expulsion of gestational sac is confirmed, patient will review post-treatment instructions about bleeding, cramping, signs of incomplete abortion, and any other pertinent medical information.
  - f. Contraception of any type may be started immediately after confirmation of abortion.
    - i. Depo-Provera injections may be given at the follow-up.
    - ii. If oral contraceptives are ordered, the patient will be given a prescription with two refills and advised to have a yearly physical and pap smear in two to three months. Patient should begin taking oral contraceptives the Sunday following her follow-up exam.

- g. If a surgical abortion was necessary, the patient will schedule a post-surgical check-up two to three weeks afterwards to ensure there were no post-operative problems.
- h. The patient will be reminded that a physician will be on-call 24 hours a day for assessment of potential complications and emergencies.

### **III. Emergency Back-Up**

- A. Patients will have access to 24-hour emergency on-call service to report complications or problems related to medical abortion.
- B. Whenever possible, the patient will be seen at Penn Family Care for treatment of problems or complications related to medical abortion.
- C. If an appropriately trained clinician is not present at Penn Family Care, the patient will be referred to back-up physicians at the Hospital of the University of Pennsylvania, who are willing to treat complications related to medical abortions.