

## Safety and effectiveness of first-trimester medication abortion in the United States

### Quick facts about medication abortion:

- Medication abortion is extremely safe.
- Medication abortion is highly effective, with a success rate over 95 percent.
- Serious adverse events occur in less than one-third of 1% of medication abortions.
- Telehealth, home administration, and provision by nurse practitioners and other clinicians have been shown to be safe, effective, and acceptable.

### Overview of medication abortion

Medication abortion is also known as medical abortion, the abortion pill, or RU486. It involves the use of two types of medications: mifepristone, which blocks progesterone needed for a pregnancy to continue, and misoprostol, which causes uterine contractions and the cervix to open to induce an abortion. Medication abortions comprise an estimated 39% of all nonhospital abortions in the US.<sup>1</sup> Mifepristone is taken either in the clinic or at home, while misoprostol is always provided for the patient to take at home.

The Risk and Evaluation Mitigation Strategy (REMS) requires, among other stipulations, that mifepristone is dispensed directly from a health care facility rather than prescribed to patients using a pharmacy.<sup>2</sup> Mifepristone is the only one of 20,000 drugs that requires clinician dispensing by the FDA.

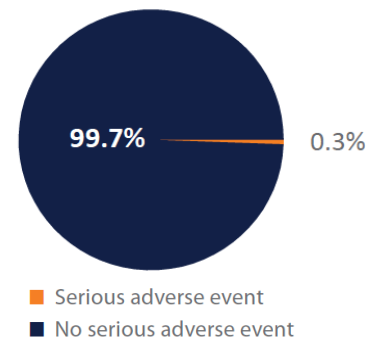
New national guidance states that medication abortion can be provided without pre-abortion ultrasounds or exams.<sup>3,4</sup> This has become especially relevant during the COVID-19 pandemic, when many providers have adopted these “no-test” protocols to help prevent the spread of COVID-19.<sup>5,6</sup> Additionally, follow-up evaluation to rule out ongoing pregnancy can be conducted without an in-person clinic visit.<sup>7-9</sup>

Medication abortion is highly safe and effective up to 11 weeks of pregnancy. Different medication abortion regimens are effective later in pregnancy. Most people having a medication abortion will experience heavy bleeding and cramping. Side effects can include nausea, vomiting, diarrhea, headache, dizziness, and fever, but these are generally tolerable and resolve without medical treatment.<sup>10-13</sup>

### Research findings on medication abortion safety and effectiveness

#### Medication abortion is extremely safe

- Nearly 4 million people in the U.S. have used medication abortion since mifepristone was first approved by the US Food and Drug Administration (FDA) in 2000 and has a strong safety record.<sup>14</sup>
- ANSIRH researchers analyzed data for 11,319 medication abortions in the California Medicaid system. This study was unique in that it captured all health care claims up to 6 weeks after the abortion at any clinical site, including emergency rooms and hospitals, and immediate and delayed adverse events. The study found that only 0.3% of medication abortions were followed by a serious adverse event.<sup>15</sup>



- Medication abortion is as safe as vacuum aspiration abortion, safer than continuing a pregnancy to term, and safer than taking many common drugs in the US, including acetaminophen (Tylenol) or sildenafil (Viagra).<sup>16,17</sup>
- Serious adverse events—cases requiring blood transfusion, major surgery, or hospital admission—are rare with medication abortion. Multiple studies have found that such events occur in less than 0.5% of medication abortions in the United States.<sup>10,15,18-20</sup>

#### Medication abortion is highly effective

- The success rate of medication abortion is 95% or higher for pregnancies up to 10 weeks.<sup>12,15,19</sup>
- For 5% of patients, additional treatments may be required such as, repeat doses of mifepristone and misoprostol, additional doses of misoprostol, or in-clinic vacuum aspiration. ANSIRH research found that among 11,319 medication abortions, 5% required the use of an in-clinic vacuum aspiration procedure or additional medications to complete the abortion.<sup>15</sup>
- Medication abortion is slightly less effective in pregnancies at later gestations.<sup>12,19</sup>

For more information about this research and other ANSIRH work, please visit [www.ansirh.org](http://www.ansirh.org).

## Further Research to Expand Access

### Screening ultrasounds and tests can be reduced or eliminated

- A recently published no-test protocol for medication abortion presents an alternate model that reduces in-clinic tests and interactions by omitting screening ultrasound when it is not indicated (see Table 1).<sup>6</sup>
- Evidence suggests that these protocols are as safe and effective as models with screening ultrasounds or tests.<sup>21,22</sup>

### Medication abortion can be provided via telehealth

- ANSIRH research on clinic-to-clinic models has demonstrated that telehealth can make medication abortion more accessible by reducing cost, distance, and transportation barriers.<sup>23,24</sup>
- Other research has demonstrated that direct-to-patient telehealth for medication abortion is comparable to in-clinic models in terms of safety and efficacy.<sup>22,25</sup>
- ANSIRH research showed that clinics increased the use of telehealth for medication abortion during the COVID-19 pandemic.<sup>5</sup>
- However, 19 states currently prohibit telehealth for medication abortion.<sup>26</sup>

### State regulations may limit who can provide medication abortion

- 32 states mandate that a physician must administer the pills for a medication abortion.<sup>26</sup> However, research has demonstrated that medication abortion can be administered safely by trained health professionals, such as physician assistants, nurse practitioners, and certified nurse midwives, which may improve access to medication abortion services.<sup>27</sup>

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Table 1. Comparison of 2016 FDA-approved protocol and no-test sample protocol for medication abortion

	2016 FDA-approved regimen	No-test sample protocol <sup>6</sup>
Maximum gestation	10 weeks of pregnancy	11 weeks of pregnancy
Screening interaction	In person	In person or via telehealth
Pregnancy dating	Ultrasound	Last menstrual period, with ultrasound dating if unsure
Screening for ectopic pregnancy	Urine pregnancy test or blood hCG test	Risk factor assessment and symptom monitoring
Mifepristone dose	200 mg orally at clinic or at home	200 mg orally at home
Method for dispensing mifepristone	In person	In person, by mail, or by mail-order pharmacy
Misoprostol dose	800 µg (4 tablets) buccally at home	800 µg (4 tablets) vaginally or buccally at home
Follow-up assessments	5–14 days after mifepristone at clinic or remote	1-week symptom check Urine pregnancy test 4 weeks after mifepristone
Minimum number of office visits <sup>†</sup>	1	0

<sup>†</sup> Depending on state law which may prohibit telehealth or require in-person tests or counseling.