PROVIDING EARLY OPTIONS

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As is common when starting any new service, many providers who have recently incorporated medical abortion into their practices have questions about coding and third party reimbursement for this service. Danco Laboratories, the licensee of mifepristone (marketed under the name Mifeprex™) in the US, is a good source of information on this subject. Their website contains a state-by-state billing and reimbursement guide that includes the reimbursement policies and procedures of many commercial insurance companies and state Medicaid programs. This state-by-state listing can be found at www.earlyoptionpill.com/hcp_reimburse.php3. What follows is an overview and answers to some common questions about billing and reimbursement reprinted largely from a guide developed by Danco.

Generally, most of the commercial payers and state Medicaid programs that cover surgical abortions are covering medical abortion with mifepristone. Since no specific CPT code has been established for the Mifeprex™ regimen, most payers are reimbursing for each component separately. For most payers, the charge for the office visits should be submitted using the appropriate E/M code (e.g. 99204 or 99214 for Day 1; 99213 or 99214 for Day 3—if your protocol includes in-office administration of misoprostol—and the follow-up visit) as supported by the documentation in the medical record. Most payers reimburse the cost of mifepristone using either a J code (e.g., J8499 or J3490) or a cost of materials code (99070). Payment will generally be a pass-through based on the actual invoice cost of the drug.

While ultrasound is not required as part of the regimen, one or more ultrasounds may be useful to verify the gestational age of the pregnancy and to determine if the pregnancy has ended. Most payers have indicated that they will reimburse for ultrasounds in accordance with their normal fee schedules. The appropriate code for an abdominal ultrasound is either 76805 or 76815 (depending on the extensiveness of the exam); the appropriate code for a transvaginal ultrasound is 76830.

Q: How do I bill for the office visits associated with the administration of Mifeprex™?
A: Reimbursement policies vary by payer. Most payers, however, are reimbursing based on the submission of Evaluation and Management codes. The office visit level must be supported by documentation in the medical record.

Q: Do I receive any reimbursement for the administration of the drug?
A: There is no separate payment for administration of Mifeprex™. The payer will generally reimburse you for the cost of the drug based on the actual invoice price. The payer will also reimburse you for additional services, such as office visits and ultrasound.

Q: Should I submit each office visit claim at the time of service or should I submit them as a batch when the course of treatment is concluded?
A: Since it is not being reimbursed as a global procedure, you can submit each bill separately as the service occurs.

Q: Can I bill for misoprostol in the same way that I do for Mifeprex™?
A: Generally, you can bill for misoprostol using a J code.

Q: How can I get additional information about coding and reimbursement?
A: You may contact Danco Laboratories for more information at 1-877-4- Early Option (1-877-432-7596) or at info@earlyoptionpill.com.

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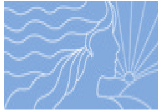

Acceptance of Medical Abortion Takes Time

Mifepristone has been available in several European countries for over a decade, and currently more than half of eligible early abortions in France, Sweden, and Scotland are performed using mifepristone regimens. The experience in these countries may provide some insight about what we might expect in the United States.

According to "Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden," by Rachel K. Jones and Stanley K. Henshaw, published in the May/June 2002 issue of *Perspectives on Sexual and Reproductive Health*, the introduction of mifepristone to European countries resulted in several important changes. First, since a medical abortion can be performed immediately after pregnancy has been confirmed, the availability of this option in the countries studied has resulted in women obtaining abortions earlier. Second, the proportion of abortions induced by mifepristone has grown steadily. Finally, and perhaps most important, there is no evidence that the availability of mifepristone has resulted in more women in these countries having abortions.

Researchers identified several factors that may slow down the acceptance of mifepristone in the United States as they did in Europe.
* Lack of funding or insurance reimbursement for early abortion services may limit the number of providers willing to provide the service.
* Delays in accessing services due to waiting periods, crowded facilities or delays in pregnancy diagnosis reduce the number of women eligible for the method.
* Providers' lack of experience with the method may result in a medical culture that does not encourage providers to offer the option, or to inform patients of its availability.

The European experience with mifepristone has been very important to practitioners in United States, as they have had time to refine the method and further document its safety and efficacy. Although there are differences between the types of facilities that provide medical abortion, availability of funding, and the cost of the procedure in Europe and the US, the European experience appears to be instructive. To read the entire article please go to http://www.guttmacher.org/pubs/journals/3415402.html.

California Medical Abortion Legislation and Other State Developments

On September 6, 2002, California Governor Gray Davis signed into law a sweeping and historic package of four pro-choice bills. Included among the bills signed by Davis was S.B. 1301, the "Reproductive Privacy Act," which codifies a fundamental right to choose and also permits licensed medical professionals in addition to physicians (e.g., advanced practice clinicians) to provide medical abortion to patients.

In contrast with the positive developments in California, negative bills restricting access to medical abortions were introduced in fourteen states (Hawaii, Indiana, Iowa, Kansas, Kentucky, New Hampshire, New Jersey, Ohio, Oklahoma, Rhode Island, South Carolina, Virginia, West Virginia, and Wisconsin). The bills proposed various restrictions, ranging from parental consent requirements, and prohibitions of public funding, to "informed consent" requirements. Of these, negative medical abortion bills were enacted in three states: Iowa prohibited state funding of medical abortion at student health centers; Kentucky prohibited health departments from distributing mifepristone, and, in a separate bill, allowed physicians to refuse to provide medical abortion; and South Carolina passed a resolution urging the FDA to reconsider its approval of mifepristone.

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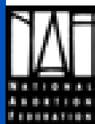
NAF is the professional association of abortion providers in the US and Canada. We serve those who make choice a reality: physicians, nurses, counselors, administrators, advanced practice clinicians and other health care professionals at medical facilities and offices in 48 states, the District of Columbia, Puerto Rico and 8 Canadian provinces. NAF is unique among reproductive health care organizations in that our mission is focused specifically on keeping abortion safe, legal and accessible.



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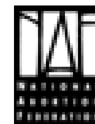
The National Abortion Federation (NAF) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.



Misoprostol News!

Applicators for Vaginal Misoprostol ("Pillguns")

To address the problem of some women's discomfort with using vaginal misoprostol, Planned Parenthood's CAPS Project Director, Lynne Randall, identified an inserter that enables women to self-administer the misoprostol tablets vaginally-all at one time-with less discomfort or worry about whether they have inserted them correctly.

Since NAF's Group Purchasing program added the pillgun to its inventory in June, approximately 780 have been ordered. As a result of the success of the pillguns, Home Prescription Services/Rx has developed pre-filled pillguns that they project will be available this month. The pre-filled misoprostol pillguns will be available in both 400mcg and 800mcg versions and can be ordered through NAF's Group Purchasing program.

Benefits of NAF'S Group Purchasing

- Offering a single source for placing and tracking orders with dozens of distributors of medical equipment and supplies
- Offering negotiated best prices for thousands of products, including mifepristone and misoprostol
- Maintaining accurate and up-to-date information on product availability, recalls, or regulations.

Many of NAF's members have reported that their savings through the Group Purchasing Programs have more than paid for their NAF membership dues.

Frequently Asked Questions about NAF's Programs and Services

1. If I am not an abortion provider, how can I refer a patient to a provider?

If you or someone you know needs information about pregnancy options, abortion, state abortion laws, or a referral to a provider of quality abortion services, call the NAF Hotline. Every month the NAF hotline receives thousands of calls from women and health care professionals from all over the U.S., Canada, and elsewhere. The NAF hotline can be reached at 800-772-9100. It is staffed by bilingual operators 8AM-10PM Eastern Time Monday-Friday, and 9AM-5PM Saturday and Sunday.

2. Does NAF sponsor any conferences?

NAF holds two national conferences per year: the NAF Annual Meeting and the NAF Risk Management Seminar. The Annual Meeting is a smorgasbord of learning opportunities, including plenary sessions, concurrent sessions, and breakfast, lunch and evening meetings, for both abortion providers (including doctors, advanced practice clinicians, nurses, counselors, and administrators) and advocates in the field of abortion rights. Physicians and other clinicians can earn Continuing Medical Education credit. Counselors and clinic administrators attend concurrent sessions designed specifically to meet their professional needs and improve their skills. Finally, abortion rights advocates, including grassroots organizers, lobbyists and attorneys working in the field of reproductive rights, come the meeting to learn how to better advance the their work.

The Risk Management Seminar focuses on clinical and practice-specific issues. Physicians, nurses, counselors, and clinic administrators attend the meeting to learn the latest developments in abortion care and to improve their skills as abortion providers. CME credit is also offered at this meeting.

NAF meetings are open to NAF members and to non-members who can provide a letter of sponsorship from a NAF member. If you have questions or are seeking further information about the NAF Annual Meeting or Risk Management Seminar, please contact NAF's Training and Education Department at 202-667-5881.

3. How can I get abortion training?

NAF maintains a Training Clearinghouse of member clinics who might be available to work with medical students, residents, or practicing physicians who want to learn more about providing abortion services.

Medical residents seeking abortion training can contact NAF for assistance in identifying a match with a NAF member clinic in his/her area. In addition, the Residency Training Program conducts periodic workshops for faculty of residency programs and representatives of NAF member clinics designed to develop and cultivate relationships and new opportunities in abortion training for residents.

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Ask An Expert!

*In our travels to throughout the country, we hear many questions from practitioners, administrators, counselors and others involved in offering medical abortion, or contemplating integrating this service into their practices. Here are the perspectives of two experienced medical abortion providers on two questions we have heard. Keep in mind, there are many different approaches to setting up medical abortion protocols and managing medical abortion patients, depending on your practice size and setting, your staffing, your clientele, your experience-level, and many other factors. Variations in the needs of individual patients and differences in the resources available to clinical providers may justify alternative approaches to those discussed below.**

Susan Cahill, PA-C, MSW *has provided abortions in Montana for over 25 years, and has participated in mifepristone clinical trials. Currently, she splits her time between her practice in Montana and at the University of Rochester, where she is continuing her involvement in mifepristone research and the provision of medical and surgical abortion services.*

Deborah Oyer, MD *is a family practitioner and medical director of Aurora Medical Services in Washington State, where she provides both medical and surgical abortions and participates in clinical studies of mifepristone. She is also a Clinical Assistant Professor at the University of Washington and trains family practice and ob/gyn residents in medical and surgical abortion.*

1. What is your protocol when a woman who is breastfeeding requests a medical abortion with mifepristone/misoprostol?

Susan Cahill, PA-C, MSW: There are no studies to help us answer this question. We know that mifepristone has a relatively short half life, and that misoprostol has a longer one, but we don't know exactly how long. The general consensus from providers whom I've consulted about this question is that most likely both medications are out of the system enough in 3 days. If the woman really wants a medical abortion, she can pump her breasts for 3 days, and then resume breast feeding. However, we do need to inform her that we do not know for sure when all the medication leaves the system.

Deborah Oyer, MD: This question has occurred only rarely in our practice. There are no data regarding the excretion of mifepristone or misoprostol into breast milk. I, therefore, base my protocol on the half-life of the drugs. Mifepristone has a half-life of about 30 hours. The circulating levels drop to an insignificant amount sometime between 48 and 72 hours after the intake of mifepristone. We use misoprostol vaginally. I have been unable to find the half-life of oral misoprostol, yet we know that the plasma concentrations are different with oral and vaginal use. There is a graph of misoprostol plasma concentration. (Absorption kinetics of misoprostol with oral or vaginal administration. Obstet Gynecol 1997;90:88-92) Extrapolating from that graph, one can assume negligible levels of misoprostol 8 to 12 hours after vaginal use.

As a result, I recommend that patients not breastfeed their children for 48 hours after their mifepristone dose, and for 12 hours after their misoprostol dose (whichever is later). I suggest they pump at their usual breastfeeding times during that time period in order to continue the milk supply. This pumped milk should be thrown away.

During the counseling for a medical abortion, I explain to patients who are breastfeeding that the medications we use during a surgical abortion are compatible with nursing. They should take this information into account when deciding whether to proceed with a medical abortion.

2. How do you proceed if an ultrasound prior to a medical abortion reveals multiple gestations?

Susan Cahill, PA-C, MSW: A twin gestation has never been listed as a contraindication to medical abortion. We have done it in our clinic without problems, and one could assume that if there had been an increase in problems with medical abortion and twin gestations during clinical trials, or in the data from France, it would be reflected in the protocol. A woman with a twin gestation should not be denied a medical abortion.

Deborah Oyer, MD: Multiple pregnancies do not change my medical abortion counseling or protocol. Mifepristone works by blocking the progesterone at the level of the progesterone receptors. This process is independent of the number of pregnancies in the uterus. Whether there is one pregnancy or more than one pregnancy in the uterus, the mifepristone will cause a breakdown in the endometrium, followed by the separation of the trophoblast(s), bleeding and cervical softening. The mechanism of action of misoprostol is to cause uterine contractions and expulsion of the uterine contents. This, too, is independent of the number of pregnancies in the uterus.

* Neither the National Abortion Federation, its officers, employees, or members are responsible for adverse clinical outcomes that might occur in the course of delivery of abortion services in which they are not expressly and directly involved in the role of primary caregiver.

Danco Issues "Dear Health Care Professional" Letter

Earlier this year, Danco Laboratories, in cooperation with the FDA, issued a "Dear Health Care Professional" letter regarding Mifeprex™. The letter reported the occurrence of six adverse events since Mifeprex™ became available in the US, reviewed the FDA-approved regimen of mifepristone/ misoprostol, and reminded providers of the importance of reporting adverse events related to Mifeprex™ to Danco and counseling patients about the risks and benefits of medical abortion. The FDA posted a copy of this letter and a detailed Q&A regarding it on their website at www.fda.gov/cder/drug/infopage/ mifepristone/.

The adverse events reported in the letter include three ruptured ectopic pregnancies (one of which was fatal), two serious systemic bacterial infections (one of which occurred during the Population Council's mifepristone trials in Canada and was fatal), and a non-fatal myocardial infarction several days after misoprostol administration. Both the FDA and the Danco letter specify that no causal relationship between any of the adverse events and the use of mifepristone has been established.

Ectopic pregnancy is a contraindication for medical abortion with mifepristone since mifepristone is not an effective treatment for that condition. Mifepristone/misoprostol has no known effects on an ectopic pregnancy and, if left untreated, ectopic pregnancy can be fatal. Infection resulting from bacteria in the vagina and cervix, although very rare, can occur in medical abortion patients. Providers should be aware of the possibility of infection in patients undergoing medical abortion and be alert to the signs and symptoms of infection. The myocardial infarction occurred in a woman several days after her use of misoprostol. She had a strong family history of early onset cardiovascular disease. A review of the literature has not identified a connection between misoprostol and cardiac incidents.

The issuing of such a letter is not unusual. In 2001, manufacturers issued at least 21 letters related to safety information or labeling changes of drugs and biologics (e.g. vaccines). As the FDA's Q&A indicates, "When the FDA receives and reviews new information, the agency routinely provides updates to doctors and their patients so that they have information on how to use a drug safely."

As stated above, both the FDA and the Danco letter specify that no causal relationship between any of the adverse events and the use of mifepristone has been established. Importantly, the FDA has not deemed it necessary to change their recommendations for use of mifepristone in response to these events. Since its approval in September 2000, it is estimated that over 100,000 women is the US have used mifepristone for medical abortion. Further, it has been used safely for medical abortion by millions of women worldwide in over a decade of use in Europe and China.

FAQ's about NAF'S Programs and Services: *continued from page 3*

5. How can I keep track of federal and state legislation?

NAF's Legislative Action Center, located online at the NAF website, summarizes abortion issues that are currently going through Congress. It allows you to access state legislation and provides monthly reports & state action alerts. The Legislative Action Center also enables you to search for your representatives on both the state and federal level and will link you to their biographies, websites and voting records. NAF's Legislative Action Center is the perfect way to stay informed on government activity related to abortion issues and reproductive health. To sign up for our "Action Alerts" or to peruse the legislative information go to www.prochoice.org and click on "Take Action".

4. How can I get information on outreach to diverse communities?

NAF's Outreach Program's bi-monthly e-newsletter is designed to share information about NAF's outreach activities, as well as a variety of programs, initiatives and helpful tools for building cultural and linguistic competency. If you would like to be added to this email list, please contact NAF at 202-667-5881 or send an email to leagilmore@yahoo.com.

Medical Abortion Technical Assistance Update

Since our Medical Abortion Technical Assistance Program began earlier this year, we have provided training and assistance to dozens of NAF member clinics across the country. NAF members interested in initiating or improving their medical abortion services have taken advantage of this specialized training by bringing NAF faculty to their clinics for half- or full-day in-services. For those members who simply have needed technical assistance over the phone, we have provided contacts to leading medical abortion experts in the field.

Here are some examples of the impact of this program in NAF clinics:

After a phone intake and counseling workshop, a NAF member clinic in Texas experienced a ten-fold increase in their medical abortion numbers. Reviewing the protocol and intake procedures with staff eliminated unnecessary barriers to care.

NAF clinics in both Maryland and Missouri increased their gestational limits for medical abortion patients to 63 days LMP after NAF- sponsored medical abortion in-services, increasing options for the women they serve.

Breaking through Barriers: Experiences Of NAF Members

Mona Reis of Presidential Women's Center in Florida:

Two years ago we were the first providers of Mifeprex in South Florida. We participated in (and even agreed to be the organizers of) the only NAF/CAPs mifepristone regional training in the state and were confident that we had everything in place to begin offering this long awaited option for women in our community.

We have had a real success in our medical abortion service. Our patients' feedback about feeling informed, prepared, and motivated has led to successful outcomes and very grateful patients. However, only a very small percentage of our patients were choosing this option. My co-director and I, unable to identify another reason for this low uptake, agreed that women in this particular region were, for some reason, not interested in this option.

After speaking with Deborah VanDerhei, a consultant with NAF's Medical Abortion Technical Assistance Program, regarding this last spring, she suggested we consider bringing a trainer to our facility to lead a workshop for our staff. I put the suggestion off for a few months, and finally decided to discuss it further. Perhaps there was some work to do that would give us the skills to present the option of Mifeprex in a different manner to trigger a wider interest.

What I had failed to realize was that, two years after our first training, 80% of my staff working with this program were new. During the workshop, led by Katy Shannon, I was stunned to recognize not only the lack of accurate information some staff had, but also the negative personal attitudes some held about this option. After four intense (yet fun) hours, telephone counselors, abortion counselors, nurses, and medical assistants were now all on the same page in our depth of understanding of the Mifeprex option, skills to present the information and an excitement to promote the option. Within our first week, our usage went from three patients to ten. Now a few weeks later, we continue to see an increase in our patients choosing this option.

In a few short months, I will celebrate my 30 year anniversary in this field. I realize that there is still so much to learn, so many new skills to acquire and challenges to continue to make our services available for all who need us.

Earn CME Credit and Learn Cutting-edge Abortion Information

The Early Options Online Continuing Medical Education (CME) Program, the ***first*** interactive web-based CME program on medical abortion, is ***now available*** on NAF's medical abortion website, www.EarlyOptions.org. Click on the "Online CME" logo to start the program.

This online CME Program:

- *Will offer health care professionals comprehensive information about the safe and effective administration of medical abortion*
- *Includes 5 modules focusing on the topics of:*
  - *medical abortion regimens*
  - *counseling*
  - *ultrasound*
  - *service delivery issues*
  - *management of side effects and complications*
- *Incorporates specific learning objectives, interactive questions and video clips from NAF's Early Options Video Series featuring expert medical abortion providers and women who have had a medical abortion to educate health care providers in the administration of medical abortion*
- *Is designated for up to 5.0 hours in Category 1 credit towards the AMA's Physician Recognition Award*

Does your clinic need medical abortion technical assistance and training?

NAF is now offering specialized technical assistance and in-services for our members who need additional training or assistance with implementing medical abortion into your current services. *If you have a training need, please complete this form and fax it back to Deborah VanDerhei at 425-672-2598.*

Are you currently providing medical abortion? ___ yes ___ no

Our clinic could use help with the following. Rank up to five topics in order of importance (1 through 5)

____ Phone intake

____ Patient Screening

____ Counseling

____ Developing protocols

____ Managing side effects and complications

____ Arranging emergency backup

____ Ultrasound training

____ Billing and Reimbursement

____ Patient agreement/consent forms

____ Legal/regulatory questions

____ Patient volume

____ Patient flow

____ Staff values clarification on medical abortion

____ MVA Training

____ On-call issues (staffing, volume, etc)

____ Other (please specify) : ______________________________

Comments:

Name

Clinic

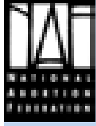
Phone

What is Technical Assistance?

As a benefit of NAF membership, assistance and training is available to support clinics that are exploring the initiation of medical abortion services as well as those with established services. These programs can be accessed either through telephone consultation or on-site training designed specifically for your staff.

Possible areas for technical assistance and in-services:

- Developing/refining protocols
- Patient volume and/or patient flow
- Medical abortion pricing/drug costs
- Paperwork (Patient Agreement, consent forms, etc)
- After hours triaging
- Patient screening
- Billing and reimbursement
- Emergency back up
- Legal/regulatory issues
- Ultrasound training
- Phone counseling/intake
- MVA training
- Managing side effects/complications
- Buy in from Medical Director, Owner, or others
- Staff values clarification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Keeping Abortion Safe, Legal, and Accessible

Change Service Requested

Post-Medical Abortion Contraception Update

In our last issue, we discussed some of the protocols NAF members are using for initiating various methods of contraception after a medical abortion. The article indicated that with hormonal methods of contraception it is important to ensure that the woman is aware she may need a back-up method of contraception for the first month, depending on when the hormonal method is started. A reader suggested that this may be an overly conservative approach even if a hormonal method is started mid-cycle. Several experts concurred. Their post-medical abortion contraceptive guidelines are that no back-up method is needed if a hormonal method is started within 5 days of passage of the pregnancy (or at a follow-up visit 1 week after initiation of the medical abortion), and that 7 days of back-up suffice if a hormonal contraceptive method is started any time after that. The World Health Organization (WHO) has published a report of an expert working group entitled *Selected Practice Recommendations for Contraceptive Use*. While it doesn't address contraception after medical abortion specifically, our experts suggested that one might reasonably assume the guidelines for initiating a method after the start of a menstrual cycle would apply to initiating a method after the passage of a pregnancy in a medical abortion. This WHO monograph can be found on-line at www.who.int/reproductive-health/publications/rhr_02_7/index.html

Danco Laboratories Releases Statistics on the 2-Year Anniversary of FDA Approval

Danco Laboratories reported in late September that more than 100,000 U.S. women have used mifepristone (marketed as Mifeprex™ in the U.S.) since FDA approval in September 2000 and product availability in November 2000. Sales in the United States are 36 percent higher for the first eight months of this year compared to last year, indicating increased use of Mifeprex™ by American women.

Current sales information reveals that clinics, such as those affiliated with the National Abortion Federation and Planned Parenthood Federation of America as well as independent clinics represent 83 percent of Mifeprex™ sales. Private practices represent 17 percent of sales. In contrast, when it first became available, virtually all sales and use of Mifeprex™ were in clinics.

Nearly one million women worldwide, excluding China where reliable numbers are not available, have used mifepristone over the last decade. Mifepristone is now approved in 26 countries.