STATE OF MARYLAND
DHMH
Office of Health Services
Medical Care Programs
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
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MARYLAND MEDICAL ASSISTANCE PROGRAM
General Provider Transmittal No. 54
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Clinics
Physicians
Hospitals
Managed Care Organizations

FROM: Susan J. Tucker, Executive Director

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal.

Medical Abortion Procedure: Termination of Early Pregnancy with Mifepristone

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The Food and Drug Administration recently approved mifepristone (Mifeprex), also known as "RU-486", for the medical termination of early intrauterine pregnancy, defined as 49 days (seven weeks) or less, counting from the beginning of the last menstrual period. As you know, under Medical Assistance, all FDA approved drugs are covered and the current coverage limitation related to abortions apply.

Mifepristone will be supplied only to licensed physicians who sign and return a Prescriber's Agreement to the distributor. It will not be available to the public through licensed pharmacies. Under the terms of the FDA approval, mifepristone may be administered only in a medical office, clinic or hospital, by or under the supervision of a physician, who is able to accurately assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

The approved treatment regimen consists of three office visits which includes the administration of the drug and appropriate follow-up. The labeling for mifepristone emphasizes that most women using the product will experience some side effects,

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primarily cramping and bleeding. The drug's labeling also warns that it should not be used in women with the following conditions:

- Confirmed or suspected ectopic ("tubal") pregnancies
- Intrauterine device (IUD) in place
- Chronic adrenal failure
- Concurrent long-term corticosteroid therapy
- History of allergy to mifepristone, misoprostol or other prostaglandins
- Hemorrhagic disorders or concurrent anticoagulant therapy
- Inherited porphyrias.

Mifeprex (NDC#6487500103) will be distributed in the U.S. by Danco Laboratories, LLC, New York, N.Y. (1-877-432-7596).

Treatment with mifepristone for the termination of pregnancy will generally require three office visits by the patient. At the first visit, the woman receives a Medication Guide which clearly explains how this option works, how to take the drug, who should avoid taking it and what side effects can occur. She is counseled by the physician and reads and signs a Patient Agreement that she has decided to end her pregnancy. She then takes three tablets, each containing 200 milligrams of mifepristone. Prescribers must also give patients clear instructions about whom to call and what to do in the event of an emergency or adverse reaction following administration of the drug. The patient returns two days later. Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan, the patient takes two tablets of the prostaglandin misoprosol each containing 200 micrograms. A follow-up visit approximately 12 days later is very important to confirm by clinical examination or ultrasonographic scan that a complete termination of the pregnancy has occurred. In the few cases where the pregnancy has not ended, a surgical termination is recommended to manage medical abortion treatment failures. Prescribers should determine in advance whether they should provide such care themselves or through others.

The administration of mifepristone will be covered by the Program on a fee-for-service basis as a medical abortion procedure. Mifepristone will not be covered as an individual medication. Since there is no CPT code for a medical abortion, CPT code 99199, "Unlisted special service or procedure," shall be used for the billing of this early termination of pregnancy option. The fee for this service is based upon three office visits to a doctor's office or clinic over a two-week period and the actual cost of the oral drugs. The fee is $401. The fee for the professional component of this service when rendered in a hospital outpatient setting is $300. Medical services provided by physicians employed by a hospital for direct patient care or by interns or residents are not billable to the Program. Physicians may not bill for office visits in addition to procedure code 99199.

"Medical Abortion" must be written on the HCFA-1500 below the procedure code in Block 24D. Diagnosis codes 635 "legally induced abortion" or 638 "failed attempted abortion" must be entered on Line 1 of Block 21. Coverage is limited to the same medical reasons as for surgical abortions and a completed Certification of Abortion DHMH 521 must be attached to the invoice. The date of service on this form shall be the date that the patient signs the Patient Agreement and takes the 600 mg of mifepristone.

Please note that the Family Planning Program does not cover abortion services and that pregnant women enrolled in the Maryland Children's Health Program are not eligible for abortion services. For recipients enrolled in a Managed Care Organization (MCO), the Medicaid Program and not the MCO will provide coverage for medical abortions. Providers must bill the Program directly for the abortion procedure. MCO physician providers may also bill the Program for this service on a fee-for-service basis. The MCO, however, is financially responsible for any related services which may be performed as part of a medical evaluation prior to the actual performance of a medical abortion.

Also note that physicians in medical office, hospital outpatient, and health and abortion clinic settings can only obtain Mifeprex directly from the distributor after signing a written agreement with the distributor.

More detailed information about this product is available on FDA's website at www.fda.gov/cder/drug/infopage/mifepristone/medguide.

Any questions regarding this transmittal should be directed to the staff specialist for physicians' services at 410-767-1722 or 1-800-685-5869, extension 1722.

SJT:rz