Medical Policy Reference Manual
Medical Policy Operating Procedure

5.01.014A Mifepristone (e.g., Mifeprex™, RU 486)

Original MPC Approval: 11/15/2000
Last Review Date: 01/01/2023
Last Revision Date: 01/01/2023

Description

Mifepristone (Mifeprex™) is used to medically terminate early pregnancy through 70 days gestation (70 days or less since the first day of a member's last menstrual period).

The FDA first approved Mifeprex™ in 2000. In 2016, the agency approved a supplemental application submitted by the drug company that markets Mifeprex™. This approval included changes in the dose of Mifeprex™ and the dosing regimen for taking Mifeprex™ and misoprostol (including the dose of misoprostol and a change in the route of misoprostol administration from oral to buccal, the interval between taking Mifeprex™ and misoprostol, and the location at which the member may take misoprostol). The approval also modified the gestational age up to which Mifeprex™ has been shown to be safe and effective, as well as the process for follow-up after administration of the drug.

The FDA approved GenBioPro, Inc.'s abbreviated new drug application (ANDA) for generic Mifeprex™ on April 11, 2019. This approval reflects FDA's determination that GenBioPro's product, Mifepristone Tablets, 200 mg, is therapeutically equivalent to Mifeprex™ and can be safely substituted for Mifeprex™. Like Mifeprex™, the approved generic product is indicated for the medical termination of intrauterine pregnancy through 70 days gestation.

The FDA-approved Mifeprex™ dosing regimen is:

- On day one: 200 mg of Mifeprex™ taken by mouth
- 24 to 48 hours after taking Mifeprex™: 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient
- About seven to fourteen days after taking Mifeprex™ follow-up with the healthcare provider.

Mifepristone blocks progesterone, a hormone necessary for pregnancy to continue. Two days later, if the pregnancy is still confirmed, 400 micrograms of misoprostol (Cytotec®) is administered (misoprostol is not administered if the first dose of mifepristone results in complete abortion). A third follow-up visit is recommended approximately 7-14 days after taking mifepristone to confirm whether the pregnancy has been terminated. If after the administration of both drugs, the member is diagnosed with an incomplete abortion (retained products of conception), then surgical intervention may be necessary.

Policy

There is no policy statement for this operating procedure.

Policy Guidelines

There are no policy guidelines for this operating procedure.

Benefit Applications

Members should check contract for available benefits.

As of 9/28/00 (the FDA approval date), benefits **are provided** for mifepristone as a **medical** benefit, unless the member's contract specifically excludes benefits for abortion care.

Additional benefits **are provided** for related office visits.

Benefits **are provided** for misoprostol (Cytotec®, the second drug) either under the member's prescription drug benefit, if the member has one, ***or*** as a medical benefit if it is given in the provider's office. **NOTE**: For FEP business, check the member's contract for benefits.

NOTE[2]: In 2022, the State of Maryland passed the Abortion Care Access Act, applicable to certain Maryland-sitused fully insured policies issued, delivered, or renewed 01/01/2023 or later. Members should check their contracts for benefits affected by this legislation. The following ICD-10 diagnostic codes may be associated with this mandate: O07.30, O07.39, O07.4, O04.80, O04.89, Z33.2.

Provider Guidelines

The FDA has not set any separate age restriction on the provision of mifepristone. State law determines whether there is any restriction on minors obtaining surgical or medical abortion care.

The U.S. Food and Drug Administration (FDA) and, the drug manufacturers of Mifeprex™ and mifepristone in the U.S. have developed specific provider guidelines for the use of the drug. These guidelines were updated as of March 29, 2016. Additionally, a Risk Evaluation and Mitigation Strategy (REMS) for mifepristone products was developed by the FDA in 2019 and revised in 2021. Under the updated guidelines, Mifepristone must be 1) prescribed by or under the supervision of a certified healthcare provider who meets certain qualifications, including signing a prescriber agreement form; 2) The healthcare provider must obtain a signed patient agreement form from the patient after counseling and prior to prescribing Mifeprex, and 3) pharmacies that dispense mifepristone must be certified.

Cross References to Related Policies and Procedures

There are no Related Policies for this Medical Policy Operating Procedure.

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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