

MEDICAL POLICY



SUBJECT: ELECTIVE MEDICAL TERMINATION OF PREGNANCY	EFFECTIVE DATE: 09/16/99 REVISED DATE: 02/21/01, 06/17/04, 04/21/05, 03/16/06 ARCHIVED DATE: 12/20/01-06/17/04, 01/18/07 EDITED DATE: 01/17/08, 01/15/09, 01/21/10, 12/16/10, 12/15/11, 12/20/12, 11/21/13
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<ul style="list-style-type: none">• <i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i>• <i>Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.</i>• <i>Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.</i>	

******This policy addresses elective medical termination of pregnancy, not incomplete abortions.******

POLICY STATEMENT:

- I. The Health Plan recognizes that physicians are legally able to use drugs for off-label indications and approves off-label indications for medications where there is sufficient medical literature and experience to support the off-label use in a cost-effective manner.
- II. Based upon our criteria and assessment of peer-reviewed literature, methotrexate, misoprostol, and mifepristone have been proven to be medically effective and therefore are **medically appropriate** for medically induced abortions.

Refer to the Pharmacy Management Policy regarding Off- label Use of FDA Approved Drugs.

POLICY GUIDELINES:

- I. Services for medically induced abortions are contract dependent.
- II. Refer to the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin #67 regarding Medical Management of Abortion.
- III. The use of methotrexate as a medical treatment for ectopic pregnancy is considered an acceptable alternative to surgery.
- IV. Patients taking mifepristone (Mifeprex, RU 486) must take misoprostol 2 to 3 days after taking mifepristone unless a complete abortion has already been confirmed before that time.
- V. Mifepristone must be administered in a clinic, medical office, or hospital, by or under the supervision of a physician able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to 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.
- VI. Prescribers of mifepristone must make sure that patients receive and have the opportunity to discuss the Medication Guide and the Patient Agreement, which is provided by the vendor.
- VII. Pregnancy termination by surgery is recommended in cases when mifepristone and misoprostol fail to cause termination of intrauterine pregnancy.

DESCRIPTION:

Methotrexate is an analogue of folic acid and a competitive inhibitor of dihydrofolate reductase. It inhibits the production of reduced folates required for de novo purine and pyrimidine synthesis, thereby interfering with DNA synthesis and cellular replication. Methotrexate is currently approved by the FDA for treating rheumatoid arthritis, psoriasis, certain cancers and gestational trophoblastic neoplasms. Methotrexate is cytotoxic and trophoblastic and interrupts pregnancy by destabilizing the trophoblastic attachment to the decidua.

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Misoprostol is a synthetic prostaglandin E₁ analog with both antisecretory and mucosal protective properties. Misoprostol is FDA approved for the prevention of NSAID (including aspirin) induced gastric ulcers in patients at high risk of complications from a gastric ulcer (e.g., elderly, patients with concomitant debilitating disease, patients at high risk of developing gastric ulceration such as those with a history of ulcer). Misoprostol produces uterine contractions, vaginal bleeding and expulsion of the products of conception, and is contraindicated in pregnant women because of its abortifacient properties. When misoprostol is used in conjunction with methotrexate, it facilitates early trimester abortion.

Mifepristone (Mifeprex), also known as *RU 486*, is a synthetic steroid with anti-progestational effects. The anti-progestational activity of mifepristone results from the competitive interaction with progesterone at progesterone-receptor sites. The compound inhibits the activity of endogenous and exogenous progesterone resulting in the termination of pregnancy. It is FDA approved for use in terminating early pregnancy (49 days or less since the patient's last menstrual period began). The labeling for Mifeprex includes a "Black Box" warning of the risks of serious bacterial infections, sepsis, bleeding and death that may occur following any termination of pregnancy, including through the use of Mifeprex.

The indication for use of Mifeprex in conjunction with misoprostol is for the termination of pregnancy through 49 days' duration of pregnancy (as dated from the first day of the last menstrual period). These drugs together disrupt pregnancy by causing decidual necrosis, myometrial contractions, and cervical ripening, leading to the expulsion of the products of conception.

RATIONALE:

Methotrexate has been effective in approximately 95% of patients with unruptured tubal pregnancy. In the United States, the use of methotrexate as a medical treatment for ectopic pregnancy is considered an acceptable alternative to surgery. Since 1982, there have been more than 25 reports, totaling more than 400 subjects who used methotrexate for ectopic pregnancy. Multiple clinical trials have been conducted that substantiate the effective use of methotrexate, combined with misoprostol as an alternative for surgical intervention for early trimester abortions.

The Food and Drug Administration approved mifepristone (trade name Mifeprex) for the termination of early pregnancy. The approved treatment regime also calls for the administration of misoprostol (400µg orally) 2 days after 600 mg of mifepristone is taken. U.S. and French clinical trials have provided safety and efficacy data for the use of mifepristone for early trimester abortions. The U.S. trials provide safety data on 859 women and efficacy data on 827 with gestational durations of 49 days or less. Success was defined as the complete expulsion of the products of conception without the need for surgical intervention. Research has supported effective alternative regimens using a lower dose of mifepristone, (200 mg) followed within 24 to 72 hours with varying routes (such as 800µg intravaginally) administered misoprostol. This regimen is at least as effective (97%), with fewer side effects, and results in more rapid expulsion.

A CDC review (Fisher, 2005) of deaths due to *C sordellii* toxic shock syndrome that occurred among previously healthy women after a medically induced abortion with 200 mg of oral mifepristone and 800 µg of vaginal misoprostol concluded that these cases demonstrate that serious infection can occur after medically induced abortion, much as it can occur after childbirth, spontaneous abortion, or surgical abortion. However, available data suggests the risk of such infection is low.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: No code(s)

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HCPCS: J8610 Methotrexate, oral 2.5 mg

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J9250	Methotrexate sodium, 5 mg
J9260	Methotrexate sodium, 50 mg
S0190	Mifepristone, oral, 200 mg
S0191	Misoprostol, oral, 200 mcg
S0199	Medically induced abortion by oral ingestion of medication including all associated services and supplies (e.g., patient counseling, office visits, confirmation of pregnancy by HCG, ultrasound to confirm duration of pregnancy, ultrasound to confirm completion of abortion) except drugs

ICD9: 633.1, Ectopic pregnancy
633.8-633.9
635.00-635.92 Legally induced abortion (code range)
V22.2 Intrauterine pregnancy
V61.7 Other unwanted pregnancy

ICD10: O00.1 Tubal pregnancy
O00.8-O00.9 Ectopic pregnancy (code range)
O04.5-O04.89 Induced termination of pregnancy with complications (code range)
Z33.1 Pregnant state, incidental
Z33.2 Encounter for elective termination of pregnancy
Z64.0 Problems related to unwanted pregnancy

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KEY WORDS:

Methotrexate, Mifepristone, Mifeprex, Misoprostol, RU 486

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) addressing Abortion. Please refer to the following websites for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=127&ncdver=2&Coverage Selection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&Keyword=abortion&KeywordLookup=Title&KeywordSearchType=And&ncd_id=140.1&ncd_version=2&show=all.&bc=gAAAABAAAAAA&](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=127&ncdver=2&Coverage+Selection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&Keyword=abortion&KeywordLookup=Title&KeywordSearchType=And&ncd_id=140.1&ncd_version=2&show=all.&bc=gAAAABAAAAAA&)