PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY/ PROCEDURE

+Policy/Procedure Number: MCUP3050 (previously UP100350)			**Lead Department: Health Services**	
Policy/Procedure Title: Medication Abortion in the First Trimester			☒ **External Policy** ☐ **Internal Policy**	
Original Date: 01/17/2001		**Next Review Date: 10/09/2025** **Last Review Date: 10/09/2024**		
Applies to:	☒ **Medi-Cal**		☐ **Employees**	
Reviewing Entities:	☒ **IQI**	☐ **P & T**	☒ **QUAC**	
	☐ **OPERATIONS**	☐ **EXECUTIVE**	☐ **COMPLIANCE**	☐ **DEPARTMENT**
Approving Entities:	☐ **BOARD**	☐ **COMPLIANCE**	☐ **FINANCE**	☒ **PAC**
	☐ **CEO** ☐ **COO**	☐ **CREDENTIALING**	☐ **DEPT. DIRECTOR/OFFICER**	
Approval Signature: *Robert Moore, MD, MPH, MBA*			**Approval Date: 10/09/2024**	

I. RELATED POLICIES:

A. MCUG3024 - Inpatient Utilization Management
B. MCUP3015 - Family Planning Bypass Services
C. MPQP1016 - Potential Quality Issue Investigation and Resolution

II. IMPACTED DEPTS:

A. Health Services
B. Claims
C. Member Services

III. DEFINITIONS:

Mifepristone REMS Program: The U.S. Food and Drug Administration (FDA) risk evaluation and mitigation strategy (REMS) for mifepristone for reproductive health indications. On January 3, 2023, the FDA permanently removed the in-person dispensing requirement and added a new pharmacy certification process, which will enable retail pharmacies that meet certain qualifications to dispense mifepristone directly to patients, in-person or by mail, who have a prescription from a certified prescriber. All other previous mifepristone REMS requirements remain in effect, including the need for prescriber certification and completion of Prescriber and Patient Agreement Forms.

IV. ATTACHMENTS:

A. Mifepristone Patient Agreement Form for Danco Laboratories
B. Mifepristone Patient Agreement Form for GenBioPro Inc.
C. Mifepristone Prescriber Agreement Form for Danco Laboratories
D. Mifepristone Prescriber Agreement Form for GenBioPro Inc.
E. Mifepristone Pharmacy Agreement Form for Danco Laboratories
F. Mifepristone Pharmacy Agreement Form for GenBioPro Inc.

V. PURPOSE:

To define the guidelines for appropriate management of medication abortions using mifepristone and/or misoprostol for first trimester medication abortions.

VI. POLICY / PROCEDURE:

A. Medication Regimens:
This policy describes Provider and Member considerations with regard to the medical management of abortion using mifepristone and/or misoprostol.

1. Effective January 1, 2022 with the implementation of Medi-Cal Rx, the pharmacy benefit is carved-out to Medi-Cal Fee-For-Service as described in APL 22-012 *Revised* "Governor's Executive Order N-01-19 regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx," and all medications (Rx and OTC) which are provided by a pharmacy must be billed to the State Medi-Cal/ DHCS contracted pharmacy administrator instead of Partnership. Please refer to the State Medi-Cal Rx webpage which is found at https://medi-calrx.dhcs.ca.gov/home/
2. Mifepristone, an antiprogestin, has been approved by the U.S. Food and Drug Administration (FDA) for termination of intrauterine pregnancies through 70 days gestation. It is generally used with misoprostol, an E1 prostaglandin analog.
    a. The usual dose is oral mifepristone 200 mg followed by misoprostol 800 mcg buccal 24 to 48 hours later. This leads to complete abortion in 94% to 98% of patients up to 63 days gestation and in 93% of patients between days 64 – 70 gestation.
    b. For patients 9 to 11 weeks gestation, a second dose of misoprostol should be self-administered after 3 to 6 hours (see Reference VII.DE. It is noted that the FDA approval does not include usage after 10 weeks gestation or a second dose.
    c. The primary complications are vaginal bleeding and crampy abdominal pain, which may be severe. Curettage may be needed to control bleeding or, after treatment failure, to terminate the pregnancy.
3. Misoprostol alone is endorsed by the World Health Organization (WHO), the American College of Obstetrics and Gynecology (ACOG) and the Society of Family Planning for medical abortions at < 11 weeks gestational age.
    a. Dosing regimens include sublingual 800 mcg every 3 hours for 2-3 doses OR intravaginal or buccal 800 mcg every 3-12 hours 2-3 doses
    b. Complications that may need follow up include heavy bleeding, pain or fever.
    c. Primary side effects include nausea, vomiting, diarrhea and fever.

B. Provider Requirements
1. Under Federal law, the FDA Mifepristone REMS Program requirements were updated on January 3, 2023 as follows:
    a. Mifepristone must be prescribed by a health care provider who meets certain qualifications and is certified under the Mifepristone REMS Program (see III.A. above).
    b. In order to become certified to prescribe mifepristone, health care providers must complete a Prescriber Agreement Form. (see Attachments B and C)
    c. The Patient Agreement Form (Attachment A) must be reviewed with, and signed by, the patient and the health care provider, and the risks of the mifepristone treatment regimen must be fully explained to the patient before mifepristone is prescribed.
    d. The Patient must be provided with a copy of the Patient Agreement Form (Attachment A) and Mifepristone Medication Guide (FDA approved information for patients.
    e. Mifepristone may only be dispensed by, or under the supervision of, a certified prescriber, or by a certified pharmacy on a prescription issued by a certified prescriber.
    f. To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form. (see Attachments D and E)
    g. Certified pharmacies must be able to ship mifepristone using a shipping service that provides tracking information.
    h. Certified pharmacies must ensure mifepristone is dispensed to the patient in a timely manner.
2. The following provider requirements must also be met for all medical abortions:
    a. The prescriber must have the ability to assess the duration of pregnancy accurately.
    b. The prescriber must have the ability to diagnose ectopic pregnancies.

c. The prescriber must be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or has made arrangements to provide such care through other appropriately trained and credentialed practitioners, and is able to assure patient access to medical facilities equipped to provide blood transfusion and resuscitation, if necessary.
d. When using Mifepristone, the prescriber has read and understood the prescribing information. Prescribing information is available on the manufacturers' websites as cited in VII.B and C. below.

3. Providers of medication abortions must be available to patients receiving this care for consultation after office hours and must have arrangements with a suitable facility for emergency surgical intervention when necessary, including after office hours.
4. The prescriber must provide each patient with a Mifepristone Medication Guide. The prescriber must fully explain the procedure to each patient, provide the patient with a copy of the Mifepristone Medication Guide and Patient Agreement form (see Attachment A), give the patient an opportunity to read and discuss, obtain the patient's signature on the Patient Agreement form, and the prescriber must sign it.
5. The prescriber should educate the patient on the importance of follow-up between 5 to 14 days after use of mifepristone to confirm that a complete termination of pregnancy has occurred and to address any complications. The prescriber must ensure there is access to schedule a follow up appointment after initiating treatment.
   a. Telephonic follow up at 5 to 14 days for evaluation of patient experience and infection symptoms (cramping, vaginal bleeding, passage of tissue, fever or discharge) in combination with an in- home pregnancy test at 4 weeks can be considered adequate.
   b. The prescriber must notify the manufacturer in writing as discussed in the Package Insert under the heading Dosage and Administration in the event of an on-going pregnancy which is not terminated subsequent to the conclusion of the treatment procedure.
   c. While serious adverse events associated with the use of mifepristone are rare, the prescriber must report any hospitalization, transfusion, or other serious event to the manufacturer, identifying the patient solely by package serial number to ensure patient confidentiality.
6. The provider must keep on file a signed Mifepristone Patient Agreement Form (Attachment A).

C. Patient Requirements
1. The patient must read carefully and understand the Mifepristone Medication Guide, which will help in understanding how the treatment works.
2. The patient must sign the Patient Agreement Form.
3. The patient should agree to see their provider between day 7 and day 14 after receiving the medication.

D. Partnership Requirements
1. Partnership will reimburse Medi-Cal providers for the service.
2. Partnership does not require prior authorization or medical justification for medication abortion services, but does require authorization for inpatient hospital services for complications arising from medication abortions when such services are medically necessary (in agreement with Partnership policy MCUG3024 Inpatient Utilization Management).
3. Abortions are considered sensitive services and as such are provided to Partnership Members in a timely manner through the Member's primary care provider (if appropriately qualified), obstetrics/gynecology (OB/GYN) specialist, or providers of family planning bypass services.

E. Partnership monitors the quality of medical abortion services through the Member grievance and appeals process or through the Plan's Potential Quality Issue (PQI) process (see MPQP1016 Potential Quality Issue Investigation and Resolution policy).

VII. REFERENCES:

A. U.S. Food and Drug Administration (FDA) "Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation" website content updated 03/23/2023
B. Danco Mifeprex (mifepristone) manufacturer's website, "For Health Professionals" tab: https://www.earlyoptionpill.com/for-health-professionals/
C. GenBioPro Inc. Mifepristone manufacturer's website, "Prescriber Resources" tab: https://genbiopro.com/resources-prescriber/
D. UpToDate: "Medication Abortion"
E. UpToDate: Bartz D, Blumenthal P. First-trimester pregnancy termination: Medication abortion published online 27 June 2022
F. American College of Obstetrics and Gynecology (ACOG), "Medication Abortion Up to 70 Days of Gestation" Practice Bulletin #225 Volume 136, No. 4, October 2020. https://www.acog.org/-/media/project/acog/acogorg/clinical/files/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-gestation.pdf
G. Medi-Cal Provider Manual/ Guidelines: Abortions *(abort)*
H. World Health Organization (WHO) 2022 Abortion Care Guideline: https://apps.who.int/iris/handle/10665/349316
I. International Federation of Gynecology and Obstetrics: Morris JL, Winikoff B, Dabash R, et al. FIGO's updated recommendations for misoprostol used alone in gynecology and obstetrics. Int J Gynaecol Obstet 2017; 138:363.
J. Department of Health Care Services (DHCS) All Plan Letter (APL) 22-012 *Revised* – Governor's Executive Order N-01-19 Regarding Transitioning Medi-Cal Pharmacy Benefits From Managed Care to Medi-Cal Rx (12/30/2022)
K. DHCS All Plan Letter APL 24-003 Abortion Services (03/28/2024)

VIII. DISTRIBUTION:
A. Partnership Provider Manual
B. OB/GYN Providers
C. Partnership Department Directors

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Chief Health Services Officer

X. REVISION DATES:
02/14/01 (Physician Advisory Committee); 09/19/01; 10/16/02, 10/20/04; 10/19/05, 10/18/06, 08/20/08; 11/28/12; 02/18/15; 02/17/16; 02/15/17; 11/15/17; *02/13/19; 02/12/20; 11/11/20; 10/13/21; 10/12/22; 10/11/23; 10/09/24

*Through 2017, Approval Date reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO: N/A