

## **Management of Miscarriage and Early 2nd Trimester Intrauterine Fetal Demise Summary & Recommended Management:**

### *Overview*

- SAB = approx. 25% of pregnancies
- Most common 1st tri complication
- 50% chromosomal
- Unlikely to be recurrent
- Usually unexplained and not preventable
- Modifiable RF: tobacco and substance cessation, folate supplementation, optimization of chronic medical conditions (e.g. improved BG control in DM)

### *Options*

- Expectant, medical, and surgical
- Hemorrhage and infection rates low for all groups
- No difference in future birth rates

### *Expectant*

- >80% will complete w expectant management alone
- May require follow up for 4wks or more to complete
- Antibiotics not needed
- Success with completion likely decreasing with increasing GA, especially beyond 8wks time
- Avoid outpatient management when >13 wks GA, proceed with caution for >11 wks GA

### *Medical*

- Up to 90% success w medical management
- Ideal dose not known, misoprostol 800mcg PV or buccal may be the most efficient
- Mifepristone 200mg PO 24hrs before misoprostol administration should be considered if available. (See Mifepristone Requirements – Medical Management)
- An additional 800mcg misoprostol dose may be repeated 3hrs to 7days after initial misoprostol
- Increased success with higher misoprostol doses, more time, and lower GA
- Antibiotics not needed
- Proceed with caution when hemoglobin is less than 10 and avoid when less than 7
- Avoid outpatient management when >13 wks GA, proceed with caution for >11 wks GA
- Followup is recommended after medical management to ensure successful completion of miscarriage.

### *Surgical*

- Successful >99%, immediate resolution
- D+C <14wks, D+E >=14wks GA
- US assist intraoperatively may help if: anomalies, challenging dilation, perforation suspected, concern about incomplete procedure, later GA

- US recommended at D+E, especially for less-experienced providers
- Antibiotic prophylaxis recommended: 200mg IV doxycycline pre-op, alternate regimen: single dose 500mg PO/IV metronidazole, single dose azithromycin 500mg
- Ensure completion with examination of POC before sending to pathology
- Complications include hemorrhage, infection, and incomplete procedures

#### *Cervical preparation*

- Medication (misoprostol and or mifepristone) or osmotic dilators (laminaria, dilapan)
- Decreases complications in some patients
- Consider <12wks adolescents or nulliparous, history of cervical surgery, obstructive cervical pathology, or prior difficult dilations
- Recommended for all women 12-14wks GA
- Strongly recommended >14wks prior to D+E
- Misoprostol buccal 400mcg 2hrs prior to procedure is recommended regimen
- Same day preparation adequate <18wks generally
- Can give higher doses of misoprostol or lengthen or shorten interval to procedure depending on clinical circumstances (parity, GA, et al)
- Advanced GA  $\geq 18$ wk, consider 2-day dilation and/or use of multiple agents
- Advanced GA D+E should be undertaken by surgeons familiar with these procedures

#### *Contraception*

- Initiate immediately after complete AB confirmed in patients desiring birth control
- Post-surgical placement of LARC is recommended
- May have higher IUD expulsion rates, but overall complications rates are low

#### *2<sup>nd</sup> trimester*

- Expectant management not recommended, but delay in initiation of IOL or D+E reasonable in medically stable patients
- D+E is preferable if experienced provider available with faster completion and fewer complications, but does not allow for intact fetus or autopsy
- Multiple regimens for medical IOL: recommended regimen of misoprostol 400mcg q6hrs (alternate regimens: load w misoprostol 800mcg, can decrease respective doses to 200mcg if side effects, can vary dosing interval to q3-6hrs)  
Adding Mifepristone 200mg PO 24hrs before misoprostol administration should be considered if available (can decrease IOL time) (See Mifepristone Requirements – Medical Management)
- Alternate medical regimens including prostin (PGF2) and Pitocin.
- IOL with misoprostol is safe <28wks, even in patients with history of uterine scar
- Retained placenta is a common complication

#### *Follow up*

- Pelvic rest for 2 weeks, or as long as patient is having vaginal bleeding
- Initiate contraception immediately in patients requesting BC
- Delay trying to conceive for one menstrual period for patients desiring pregnancy
- BHC referral as needed

- Discuss and improve modifiable RF and preconception counseling

## **Literature Review and Discussion:**

### **Definition**

Pregnancy loss refers to pregnancies <20 weeks gestation that end in spontaneous abortion, or miscarriages. Pregnancy loss can also apply to intrauterine fetal demise  $\geq$  20wks, or stillbirths. Early pregnancy loss is defined as crown-rump length of  $\geq$ 7 mm and no heartbeat; mean sac diameter of  $\geq$ 25 mm and no embryo; absence of embryo with heartbeat  $\geq$ 2wks after scan that showed gestational sac without yolk sac; and absence of embryo with heartbeat  $\geq$ 11 days after scan that showed gestational sac with a yolk sac. This guideline focuses on the management of pregnancy loss in the first trimester and early second trimester <20wks. There is brief discussion of management of intrauterine fetal demise >20wks GA. Late second trimester fetal demise at gestational ages >24wks GA are managed similarly to stillbirth. **Stillbirth** is discussed in a separate guideline. **First trimester vaginal bleeding** with diagnosis and management of pregnancies of undetermined location is reviewed in a separate guideline. **Recurrent pregnancy loss** is discussed in a separate guideline.

### **Background**

Spontaneous abortion, or SAB, is the most common first trimester pregnancy complication. Up to 25% of pregnancies end in miscarriage, although many of these are too early to be commonly recognized and diagnosed formally. Incidence of SAB decreases with increasing gestational age with <1% of SAB occur beyond 15wks GA (in chromosomally and structurally normal feti). Most SAB occur in patients with no risk factors. The most common associated risk factors are increasing maternal age, prior SAB, and tobacco use. The most common etiology of SAB is a chromosomal abnormality, accounting for 50% of miscarriage, although many losses remain unexplained. Many patients will associate other causes like recent falls and trauma, stress, heavy lifting or exertional exercise but there is no evidence to support these correlations. Therefore, reassurance should be provided to help dispel myths, and relieve the patient's feeling of responsibility. Primary prevention of SAB is with prenatal care and preconception counseling, although since most are chromosomal, most SABs cannot be prevented.

### **Diagnosis and Definitions**

The diagnosis of SAB is generally made after patients present with vaginal bleeding and cramping but can also be made during an early ultrasound for gestational dating. Clarification of the diagnosis of early pregnancy failure and loss with ultrasound criteria for diagnosis is discussed in the **First trimester bleeding** guideline.

Many women presenting with vaginal bleeding and cramping will be diagnosed with *threatened abortions* or normal ultrasounds with a closed cervix. These are managed expectantly with interval follow up in the next 1-2 week for repeat US.

Confirmed spontaneous abortions fall into subcategories: *incomplete abortions* have some or all products of conception passed, *inevitable abortions* will have vaginal bleeding with an open cervix, finally "*missed abortion*" is better defined as either an anembryonic gestation (or

“blighted ovum”) if the GS is empty, or an embryonic (<10wk) or early fetal demise (>10wk) if the fetal pole has no heartbeat. *Septic abortion* refers to spontaneous abortion with associated intrauterine infection. *Spontaneous abortion* is complete with passage of all intrauterine tissue.

### **Workup**

Upon confirmed diagnosis, history should be completed as well as pelvic exam to assess cervix and US to clarify gestational age. Decisions regarding the management of the pregnancy are based upon the US GA and not the GA by LMP. Rh testing should be confirmed for all patients. Rh isoimmunization can occur from pregnancies resulting in SAB. For Rh negative patients, MICRhoGAM can be given to patients <12wk6d GA, and full dose Rhogam should be given to patients  $\geq$ 13wk GA. Other tests may be completed as appropriate: e.g. STD screening if risk factors, RPL labs if indicated, IUFD labs if indicated. The diagnosis of SAB can be emotionally overwhelming for patients. The diagnosis is best made expeditiously, directly, empathically, and ideally in-person. BHC should be offered. Patients that desire contraception should have methods initiated immediately after the pregnancy is complete.

### **Expectant Management**

Expectant management is reasonable in patients <13wks GA with stable vital signs, no evidence of infection, and no active hemorrhage. Proceed with caution with >11wks GA and appropriately counsel about bleeding precautions and that they may be seeing fetal parts. There is not good data on expectant management greater than 8wks time, thus it is not recommended. Expectant management is successful in 80-90% of patients, with increased success with more time, if diagnosed with an incomplete abortion, and if already experiencing bleeding and cramping. By 2wks from diagnosis, 30% are complete. At 4wks from diagnosis, 90% of incomplete, 75% of missed, and 66% of anembryonic SABs will be complete.

### **Medical Management**

Medical management can be considered as first line for SAB management, or after failed expectant management. Medical management may be less optimal in patients with infection, severe anemia, an inability to follow up and actively anti-coagulated or with bleeding disorders, and those with organ failure. Proceed with caution when hemoglobin is less than 10 and avoid when less than 7. Proceed with caution with >11wks GA and appropriately counsel about bleeding precautions and that they may be seeing fetal parts. Avoid >13 wks GA for outpatient management. Contraindications to medical therapies include allergy to prostaglandin medications and in patients with suspected gestational trophoblastic disease.

Varying regimens for medical management of SAB have been described using multiple different pharmacologic agents, doses, routes, and timing. Misoprostol (PGE1) is the most well-studied agent and can be administered via multiple routes: PO, buccal, SL, PV, or PR with sublingual and buccal administration having similar pharmacokinetics to vaginal. Vaginal overall appears to have higher success rates and less side effects. Common misoprostol side effects are gastrointestinal (N/V/D), fever, and mild rigors. The type of pregnancy also may effect success rates, with anembryonic SAB achieving completion with medical management 80% of the time, versus almost 90% success with incomplete SAB.

High success rates with overall low side effect profiles have been described with the following regimen: ACOG: 800mcg misoprostol vaginally for one dose, with repeat dose no sooner than 3hrs, but up to 7 days later. This dosing is also considered safe in women with prior uterine scars, including prior cesarean deliveries. Antibiotics are not recommended for medical SAB management.

### Mifepristone

The addition of 200mg mifepristone 24 hrs before misoprostol administration significantly improves treatment efficacy as demonstrated by an RCT in 2018, leading to higher completion rates without need for surgical intervention. Thus the combination of mifepristone with misoprostol is superior to misoprostol alone and should be offered preferentially when mifepristone is available. (Of note: mifepristone is contraindicated in women taking high-dose systemic steroids).

Mifepristone is under an FDA Risk Evaluation and Mitigation Strategy (REMS). It requires:

- Administration to the patient by the provider
- Two forms involved with the administration process.
- Use of .dotphrase in Cerner (see Appendix 2)

### **Follow-up after Expectant or Medical Management**

Strict pelvic rest is advised until SAB completion is confirmed. Pain and bleeding is expected during pregnancy passage, but should not exceed 2-3 hrs of soaking pads with uterine bleeding and passage of large clots. Continued heavy bleeding beyond 2-3hrs, uncontrolled pain, or continued orthostatic symptoms should prompt follow up. Fever can occur as a misoprostol side effect, especially at higher doses. However, fever accompanied by malodorous discharge, worsening pelvic or abdominal pain, or worsening systemic infection symptoms should also prompt follow up. After expectant or medical management, follow up should be done to confirm complete SAB. Follow up can be getting a descriptive history, a ultrasound to confirm that gestational sac is no longer present, or hcg levels with decline >50% from baseline at 48hrs. Patients will often describe an episode of bleeding and cramping, with passage of tissue, and then improvement and then resolution of symptoms. Unless GTD is suspected, serial measurements of HCG until zero are not recommended for routine follow up of expectantly or medically managed asymptomatic SAB patients. If SAB is not complete at follow up, then continued expectant management for another 1-2 week, repeat medical management, or surgical management may all be options.

### **Surgical Management**

Surgical management is preferred for unstable patients, and those with septic abortions, hemorrhage, coagulopathy, or who do not have access to emergency follow up. Surgical management results in shorter time to completion, decreased bleeding, decreased risk of transfusion, and decreased need for unexpected readmission. Surgical management of SAB results in immediate completion in >99% of patients with very low complication rates, approximately 1%.

Surgical SAB management is achieved with dilation and curettage (D+C) <14wks GA, and dilation and evacuation (D+E) >=14wks GA. Cervical dilation, either mechanical or by other

means, is followed by suction of the intrauterine contents, finally concluding with curettage. Suction for D+C can be provided by either electric vacuum aspirator machine, or by manual vacuum aspiration (MVA). D+C can be performed safely in the outpatient setting or in the operating room. Office D+C procedures can be done with the MVA with local paracervical block alone, or with mild sedation (PO or IM). D+C is most commonly performed in the OR w IV sedation, with or without paracervical block. Overall, MVA is equivalent to EVA at <10wk GA with no difference in complications such as infection, hemorrhage, or pain. MVA is quieter and may cause less pain and perforation, although this may be provider proficiency related. EVA and MVA utilize the same pressure, although the flexible cannulas often used with MVA may be less traumatic and lead to fewer uterine perforations.

ACOG recommends preoperative antibiotics prior to surgical management of SAB. Doxycycline 200mg IV or PO 1hr prior to procedure is recommended, however, alternative regimens can be considered. These include single dose metronidazole 500mg or single dose azithromycin 500mg.

Cervical dilation can be achieved with mechanical dilators (Pratt, Hagar, or Denniston surgical instruments), osmotic dilators (dried seaweed laminaria, or synthetic dilapan - absorb water from the cervix and increase in size), or pharmacologic agents (misoprostol and mifepristone). The latter two methods take time, either hours or days, prior to achieving dilation. None of these methods increases infection risk. Cervical preparation aims to ease dilation to decrease risk of cervical trauma, decrease risk of perforation, and to decrease risk of inadequate dilation leading to incomplete procedure. Cervical preparation prior to mechanical dilation is recommended for some women before D+C, and in all women before D+E. Consider preparation in women who are adolescents, nulliparous, have a history of cervical procedures (excision w LEEP or CKC, or cerclage), obstructive cervical pathology (stenosis or fibroid), or prior difficult dilations, and for surgeons with less experience. Cervical preparation is recommended for all women 12-14wks GA and strongly recommended >14wks prior to D+Es. Misoprostol alone, 2-4hrs before procedure, can result in adequate cervical preparation prior to D+C. Doses from 200mcg-800mcg has been used, but 400mcg at least 2hrs prior to procedure is recommended. Dilapan osmotic dilators are equally effective to misoprostol for same-day cervical preparation, but may be more uncomfortable. At GA  $\geq$ 14wk but <18wks, same day cervical preparation is adequate in most patients. However, for D+E >14wks, 200mg mifepristone given 24hrs prior to procedure in addition to 400mcg misoprostol 2 hrs prior to procedure provides more dilation than misoprostol alone and can be considered. For D+E at GA >18wks, a two-day procedure may be preferable to achieve more dilation. Laminaria or dilapan may be placed the day before the procedure, with or without addition of misoprostol the day of the procedure. If osmotic dilators are used, the number should be recorded, and all should be accounted for at time of removal and surgery. At GA >20wks, adequate cervical preparation often requires multiple agents and may take more than 2 days. [Table 1].

Overall, surgical management has a very low complication rate/ 1-5% of procedures encounter minor complications including infection, cervical trauma, retained products, hematometra or increased bleeding. Major complications are encountered  $\leq$ 1% of surgical procedures and include significant hemorrhage, perforation, sepsis, and maternal mortality. Hemorrhage at D+C is most commonly caused by incomplete procedure or uterine atony. If retained POCs is suspected, US can be used to assist with D+C completion and the tissue can be examined to

ensure it is complete. Significant hemorrhage at D+C should be treated similarly to PPH. IVF and labs are indicated, and blood transfusion considered. Bimanual massage should be performed, bladder emptied, and uterotonics administered. Methergine 0.2mg IM or intracervical, Misoprostol 1g PR, Oxytocin 20-40U IV or 10U IM, or vasopressin 4-6U intracervical can be given. If bleeding does not respond to uterotonic agents, and the uterus remains enlarged and boggy, then placement of an intrauterine 30cc foley balloon can be considered. If bleeding continues in the setting of a well-contracted uterus, then the cervix and lower genital tract should be examined for laceration or uterine perforation. If perforation is suspected, then intraoperative US is indicated to clarify the location of the perforation site. If the procedure is complete, the patient is stable, and bleeding is minimal, then some perforations can be managed conservatively. However, if pelvic organ injury is suspected, especially in cases where suction may have entered the intrauterine cavity, or if the patient is unstable, then laparoscopy or laparotomy may be indicated.

If the patient desires contraception, this should be initiated right away. LARC are considered first-line contraceptive methods. Implants can be placed in the operating room after completion of D+C. IUDs can be placed immediately post-D+C. Other hormonal contraceptives can be initiated immediately without increased side effects or complication rates.

### **Management of 2nd Trimester Pregnancy Loss**

Expectant management is not generally recommended for 2nd trimester pregnancy losses due to risk of DIC and uncontrolled complication. 2nd trimester pregnancy loss management depends on provider experience.

At GA  $\geq$ 14wk and  $<$ 16wk, surgical management with D+E is preferable, leading to completion faster, with less pain, less bleeding, fewer infections, and decreased risk of retained placenta or pregnancy tissues, and fewer overall complications. At GA  $>$ 16wks, medical management or D+E can be considered, depending on provider experience. Pregnancy loss  $>$ 24wks is managed similarly to stillbirth.

Patients can be offered medical management of 2<sup>nd</sup> trimester pregnancy loss with medical induction in the hospital. Please see the **Stillbirth** guideline for further details.

### **Follow up After Pregnancy Loss**

Generally, patients are advised to be on pelvic rest for 2 weeks after surgical procedures however no specific studies have shown it to decrease risk of infection. Restrictions include: no tampons, no tub baths, no douching, no swimming, and no vaginal intercourse. Contraception should be addressed, and in patients not actively trying to conceive. In patients trying to conceive, a prolonged delayed inter-pregnancy interval has not been shown to decrease adverse pregnancy outcomes; however, for practical purposes a delay in attempting conception until after the next normal menstrual cycle is a reasonable recommendation. BHC referral should be offered to all patients. Providers should have a nonjudgmental discussion of modifiable risk factors (e.g. tobacco cessation, diabetic blood sugar control) and given reassurance that SAB is common (25% if pregnancies) and not generally preventable (50% chromosomal). Recurrence of SAB is approximately 14% after 1 SAB, and  $<$ 30% after 2 or 3 SABs.

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**Appendix 1**

**Cervical preparation and POC Examination**

Table 1

**Cervical Preparation**

D+C <14wk GA	Cervical Preparation Recommended: 400mcg buccal miso 2hrs pre-procedure
<12wks	Consider for: <ul style="list-style-type: none"> <li>• Adolescents, nulliparous</li> <li>• H/o cervical surgery</li> <li>• Cervical pathology</li> <li>• Known prior difficult dilation</li> <li>• Less experienced surgeons</li> </ul>
12-14wk	<ul style="list-style-type: none"> <li>• Recommended</li> </ul>
D+E >14wk GA	Cervical Preparation:
>14-18wks	400mcg-800mcg buccal miso at least 1.5hr pre-procedure +/- addition of osmotic dilator Same day <ul style="list-style-type: none"> <li>• Strongly recommended for all women</li> </ul>
>18wks	400mcg-800mcg buccal miso at least 1hr pre-procedure + addition of osmotic dilator 2 day <ul style="list-style-type: none"> <li>• Strongly recommended for all women</li> </ul>

Table 2

**POC Examination**

Tissue Type	Expected Findings
Gestational sac	Thin, transparent, identified in pregnancy <12wk <ul style="list-style-type: none"> <li>• 6wk = dime size</li> <li>• 7wk = nickel size</li> <li>• 8wk = quarter size</li> </ul>
Chorionic villi	Transparent w frond-like projections, will float, turns bone-white with heated water or vinegar
Fetal parts	<ul style="list-style-type: none"> <li>• &lt;9-10wk: villi, GS</li> <li>• 10-13wk: villi, GS, some fetal parts</li> <li>• 12-13+wks: villi, placenta, GS, all fetal parts – calvarium, spine, four extremities</li> </ul>
Decidual tissue	Opaque, red-brown-grey, does not float

## Appendix 2

### Mifepristone Administration

Mifepristone is under an FDA Risk Evaluation and Mitigation Strategy (REMS).

Requirements:

- Administration of medication by the provider to the patient
  - Provider needs to observe the patient take medication as per the FDA
- One form involved with the administration process.
  - Mifeprex Patient Agreement (see below)
  - this needs to be signed and scanned into Cerner
- Use of Dot phrase in Cerner (see below)

Mifepristone Dot phrase:

-I have fully explained the procedure to this patient, provided her with a copy of the Medication Guide and PATIENT AGREEMENT, given her an opportunity to read and discuss them, obtained her and my signature on the MIFEPRISTONE PATIENT AGREEMENT, and scanned it into the EHR.

-The patient's follow-up visit has been scheduled approximately in 7-14 days to confirm that the spontaneous abortion is complete and there have been no complications.

-While serious adverse events associated with the use of Mifeprex are rare, I will report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.

-The package serial number for this Mifeprex is \_\_\_\_\_

### **PATIENT AGREEMENT**

Mifeprex\* (mifepristone) Tablets

NB:

How to navigate to the ANMC Document page? (see below)

The current version of the Mifepristone patient agreement is now uploaded to the document library.

The link will take you to the list of "other consents" in the document library so that you can see how it is listed.

[Health Information Management – Health Record Approved Forms \(anthc.org\)](http://anthc.org)

You can access it through the ANMC home page via Support and navigate to the ANMC Health Record Approved Forms and References> Consent> Other Consents

### ANMC Health Record Approved Forms and References

<http://share.home.anthc.org/anmc/him/SitePages/Health%20Record%20Approved%20Forms.aspx>

### Consent form: Mifepristone patient agreement

[http://share.home.anthc.org/anmc/him/Health%20Record%20Approved%20Forms/Consent/Other%20Consents/Mifepristone\\_Patient%20Agreement\\_3-2021.pdf](http://share.home.anthc.org/anmc/him/Health%20Record%20Approved%20Forms/Consent/Other%20Consents/Mifepristone_Patient%20Agreement_3-2021.pdf)

## PATIENT AGREEMENT FORM

Mifepristone Tablets, 200mg

**Healthcare Providers:** Counsel the patient on the risks of mifepristone. Both you and the patient must sign this form.

### Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
  - a. I understand I will take mifepristone on Day 1.
  - b. My provider will either give me or prescribe for me the misoprostol tablets, which I will take 24 to 48 hours after I take mifepristone.

2. My healthcare provider has talked with me about the risks, including:
  - heavy bleeding
  - infection
  - ectopic pregnancy (or pregnancy outside the womb)
3. I will contact the clinic/office right away if in the days after treatment I have:
  - a fever of 100.4°F or higher that lasts for more than four hours.
  - severe stomach area (abdominal) pain
  - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
  - stomach pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol.
4. My healthcare provider has told me that these symptoms could require emergency care. If I cannot reach the clinic or office right away, my healthcare provider has told me who to call and what to do.
5. I should follow up with my healthcare provider about 7 to 14 days after I took mifepristone to be sure that my pregnancy has ended and that I am well.
6. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
7. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
8. I have a MEDICATION GUIDE for mifepristone. I will take it with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone.
9. My healthcare provider has answered all my questions.

**Patient Signature:** \_\_\_\_\_ **Patient Name (print):** \_\_\_\_\_ **Date:** \_\_\_\_\_  
 \_\_\_\_\_

The patient signed the PATIENT AGREEMENT in my presence after I counseled the patient and answered all questions. I have given the patient the MEDICATION GUIDE for mifepristone.

**Provider's Signature:** \_\_\_\_\_ **Name of Provider (print):** \_\_\_\_\_  
**Date:** \_\_\_\_\_

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before the patient leaves the office and put 1 copy in the medical record.

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