**PURPOSE**

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To provide indications, contraindications and process for use of misoprostol for purposes of cervical ripening in the outpatient setting.

**SUMMARY**

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The goal of outpatient cervical ripening is to improve the likelihood of presentation with spontaneous labor and avoid an induction of labor.  A secondary goal is to improve the favorability of the cervix for an induction if one is required.  This guideline focuses on late term inductions of labor but could be applied in other circumstances where cervical ripening is desired but a formal induction of labor is not required.

**GUIDELINE INFORMATION**

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**GENERAL INFORMATION:**

The process and concerns for an induction of labor have been outlined by ACOG in both the guidelines to perinatal care as well as in Practice Bulletin 107, “Induction of Labor” published in 2009 and reaffirmed in 2013.1,8  These documents outline the indications and process for cervical ripening and induction of labor.  Outpatient cervical ripening is described as an option as well.

If the cervix is unfavorable for induction, cervical ripening may be beneficial and should be considered. The status of the cervix can be determined by the Bishop pelvic scoring system (See Appendix A).  An unfavorable cervix has been defined most commonly as a Bishop score of 6 or less in most randomized trials.  The goal of cervical ripening is to facilitate the process of cervical softening, thinning, and dilating with resultant reduction in the rate of failed induction and induction to delivery time. If induction is indicated and the status of the cervix is unfavorable, agents for cervical ripening may be used.

Several published studies and meta-analyses have been performed for outpatient cervical ripening.  A study by Gaffaney, et al. found that daily administration of 100 mcg of oral misoprostol compared to placebo in pregnancies at 40-42 weeks decreased the time to admission and time to delivery as well as decreasing the number of women remaining undelivered at the end of the 72 hour study period.6  Another study by McKenna showed that a single dose of 25 mcg vaginal misoprostol decreased the interval to delivery in women with an unfavorable cervix at term.9Misoprostol has been found to be more effective than dinoprostone (Cervidil) for cervical ripening and induction of labor.3  A meta-analysis in the Cochrane Database found misoprostol to be as effective as other means of cervical ripening while decreasing the risk for cesarean delivery. 2, 7

Misoprostol (Cytotec), a synthetic PGE1 analogue, can be administered for cervical ripening either intravaginally, orally or buccally.  There is extensive clinical experience with this agent and a large body of published reports supporting its safety and efficacy when used appropriately.  Misoprostol has been shown to be as effective as other cervical ripening agents with lower cesarean delivery rates.  Misoprostol is approved by the FDA for the treatment of peptic ulcer disease in individuals who are not pregnant.  As of November 2012, the package insert for misoprostol includes the following information about the drug’s Obstetrical use:

*Cytotec can induce or augment uterine contractions. Vaginal administration of Cytotec, outside of its approved indication, has been used as a cervical ripening agent, for the induction of labor and for treatment of serious postpartum hemorrhage in the presence of uterine atony. A major adverse effect of the obstetrical use of Cytotec is hyperstimulation of the uterus which may progress to uterine tetany with marked impairment of uteroplacental blood flow, uterine rupture (requiring surgical repair, hysterectomy, and/or salpingo-oophorectomy), or amniotic fluid embolism. Pelvic pain, retained placenta, severe genital bleeding, shock, fetal bradycardia, and fetal and maternal death have been reported.*

*There may be an increased risk of uterine tachysystole, uterine rupture, meconium passage, meconium staining of amniotic fluid, and Cesarean delivery due to uterine hyperstimulation with the use of higher doses of Cytotec; including the manufactured 100 mcg tablet. The risk of uterine rupture increases with advancing gestational ages and with prior uterine surgery, including Cesarean delivery. Grand multiparity also appears to be a risk factor for uterine rupture.*

*The effect of Cytotec on the later growth, development, and functional maturation of the child when Cytotec is used for cervical ripening or induction of labor have not been established. Information on Cytotec’s effect on the need for forceps delivery or other intervention is unknown.*

**GUIDELINE:**

1. For patients who reach 41 weeks gestational age, a determination of the cervical favorability is made at an office visit.
	1. For patients with a favorable cervix, either expectant management with serial antenatal testing or induction of labor may be pursued.
	2. For patients with an unfavorable cervix, either expectant management with serial antenatal testing or outpatient cervical ripening can be pursued (See Appendix B for flow-chart)
2. For patients who are are undergoing a medically indicated induction and who have no contraindications (see 3f and 3g), a determination of the cervical favorability is made at an office visit.
	1. For patients with a favorable cervix, induction of labor may be pursued
	2. For patients with an unfavorable cervix, outpatient cervical ripening may be pursued
3. For patients undergoing cervical ripening, the patient should be assessed for eligibility for administration of misoprostol.  This assessment should include documentation of:
	1. Gestational age (use of misoprostol for induction is contraindicated at less than 39 0/7 completed weeks, unless a medical reason exists to justify earlier delivery)
	2. Bishop score
	3. Clinical adequacy of the maternal pelvis
	4. Estimated fetal weight, by Leopold’s maneuvers or ultrasound
	5. Presenting fetal part
	6. Absence of contraindication to vaginal delivery (e.g., placenta or vasa previa, transverse lie, previous classical Cesarean delivery, active genital herpes, previous extensive uterine surgery)
	7. Reassuring fetal status.  Non-reassuring fetal heart tracing, oligohydramnios, growth restriction, or other questionable fetal status are generally contraindications to outpatient cervical ripening
4. The patient should be counseled regarding the use, risks and benefits to labor induction and misoprostol, including informing the patient of current FDA labeling of misoprostol.
5. Patients who opt for outpatient cervical ripening will be booked through triage.
6. When a patient presents for outpatient cervical ripening, the preferred area will be MSCU where the patient will have initial assessment and external fetal monitoring initiated.  (NOTE: location for assessment and monitoring is preferred in MSCU but an alternative location may be discussed through the collaborative discussion between the BU Charge nurse, MSCU team leader and physician/CNM.  Staffing, patient acuity and other factors should be considered if alternate location is determined to be necessary)
	1. If uterine tachysystole is noted or if the patient is clinically in labor, misoprostol should not be administered under this protocol.
7. The provider will review the process of outpatient cervical ripening and obtain consent prior to initiating the process. (see attached consent)
8. After achieving a Category 1 Non-Stress Test, 25 mcg misoprostol may be administered orally, buccally or vaginally per physician/CNM order.
9. Following administration of misoprostol, the fetal heart rate and uterine activity will be electronically monitored for 60 minutes.
10. If the fetal testing is Category 1 Non-Stress Test, the patient will be sent home with an appointment to return either:
	1. 4 hours later to assess need for a second dose of misoprostol

**OR**

1.
2. b.   Within 24 hours for assessment and determination of plan of care related to additional misoprostol administration or admission for induction.
3. c.  The patient will be provided post procedure instructions including when to return or notify their provider.

10.  If fetal testing is not Category 1, notify OB provider for additional assessment/interventions.

APPENDIX A

Bishop Score

From “Induction of Labor,” ACOG Practice Bulletin 107, Published 2009, Reaffirmed 2013.

APPENDIX B:

Late Term Algorithm - \*\* Buccal misoprosol administration is also acceptable for outpatient cervical ripening

**REFERENCES**

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1.        ACOG Guidelines for Perinatal Care, Seventh Edition, Copyright October 2012, by the American Academy of Pediatric sand the American College of Obstetricians and Gynecologists
2.        Alfirevic Z, Weeks A.  “Oral misoprostol for induction of labour (review)” Cochrane Library 2010, Issue 1.
3.        Austin SC, Sanchez-Ramos L, Adair D. “Labor induction with intravaginal misoprostol compared with the dinoprostone insert: a systematic review and metaanalysis” Am J Obstet Gynecol, 2010; 202: 624.e1-9.
4.        Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964; 24: 266-8
5.        Doswell T, Kelly AJ, Livio S, Norman JE, Alfirevic Z. “Different methods for the induction of labour in outpatient settings (Review)” Cochrane Library 2010, issue 8.
6.        Gaffaney CA , Saul LL, Rumney PJ, Morrison EH, Thomas S, Nageotte MP, Wing DA. “Outpatient oral misoprostol for prolonged pregnancies: a pilot investigation.” Am J Perinatol, 2009; 26(9): 673-7.
7.        Hofmeyr GJ, Gulmezoglu AM, Pileggi C.  “Vaginal misoprostol for cervical ripening and induction of labour (Review)” Cochrane Library, 2013, Issue 1.
8.        “Induction of Labor.”  ACOG Practice bulletin No. 107. American College of Obstetricians and Gynecolgists. Obstet Gynecol 2009; 114: 386-08.  Reaffirmed 2013.
9.        McKenna D, Ester JB, Proffit M, Waddell K. “Misoprostol outpatient cervical ripening without subsequent induction of labor: a randomized trial.” Obstet Gynecol, 2004; 104: 579-84.

**RELATED DOCUMENTS**

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**GENERAL INFORMATION**

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| **Notification Schedule:** |  |
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APPENDIX A



APPENDIX B

