POLICY:	**Cervical Ripening**
Program Area:	**Obstetrics**
Section:	**General**
Reference Number:	**CLI.5810.PL.005**
Approved by:	**Regional Lead – Acute Care & Chief Nursing Officer**
Date:	Issued 2015/Sept/17 Revised 2024/Nov/01

PURPOSE:

The purpose of this guideline is to promote the effective and safe use of Cervical Balloon Catheters, Vaginal Misoprostol suppositories, Cervidil® and Prostin® for cervical ripening.

BOARD POLICY REFERENCE:

Executive Limitations (EL-01) Global Executive Restraint & Risk Management
Executive Limitations (EL-02) Treatment of Clients

POLICY:

When indicated, cervical ripening is offered when the Modified Bishop score is less than 7, except in term pre-labour rupture of membranes. If the modified Bishop score is greater than or equal to 7 and indication of induction is warranted, induction of labour is recommended following the CLI.5810.PL.002 Induction and Augmentation of Labour guideline.

DEFINITIONS:

Bishop Score – a method used to evaluate the likelihood of a successful induction of labour based on the patient's cervical characteristics. A score of less than 7, indicates an unfavorable cervix and cervical ripening is recommended.

Modified Bishop Scoring System			
Score	**0**	**1**	**2**
Dilatation (cm)	0	1-2	3-4
Cervical Length (cm) (previously effacement)	Greater than or equal to 4 (0-30%)	2-3 (31%-50%)	Less than 1-2 (51%-80%)
Consistency	Firm	Medium	Soft
Position	Posterior	Mid	Anterior
Station	-3	-2	-1/0

Burnett JE Jr. Preinduction scoring: an objective approach to induction of labor. Obstet Gynecol 1966;28:479–83.

Active Labour – regular uterine contractions approximately every 3-5 minutes (2-5 contractions averaged over 10 minutes) of sufficient strength to cause cervical dilatation and/or effacement. Traditionally diagnosed when the cervix is 3-4 cm dilated in nulliparous patient or 4-5 cm dilated in a multiparous patient (S. Moola, 2018).

Cervical Ripening – the use of mechanical or pharmaceutical means to soften, efface, and dilate the cervix prior to induction of labour (IOL) to increase the likelihood of a successful vaginal birth (Robinson, d. et al., 2023).

Grand-multiparity – parity greater than or equal to 5.

Induction of Labour (IOL) – the artificial initiation of labour before it's spontaneous onset (Robinson, d. et al., 2023).

Primary Care Provider (PCP) – a regulated healthcare professional, who has the overall responsibility for directing and coordinating the care and management of a patient. The PCP will refer to obstetricians, family physicians and midwives.

Tachysystole – abnormal labour contraction patterns, which include any of the following criteria:

- More than 5 contractions in any 10-minute period averaged over 30 minutes; **OR**
- Contraction duration of more than 90 seconds; **OR**
- Coupling or tripling of contractions (two or three contractions in a row with little or no rest in-between), resulting in an overall duration of greater than 90 seconds; **OR**
- Resting period between contractions is less than 30 seconds; **OR**
- Absence of resting tone (or uterus remaining firm) between contractions assessed by palpation; or intrauterine pressure greater than 25 mmHg by IUPC between contractions (Dore, S. & Ehman, W., 2020).

IMPORTANT POINTS TO CONSIDER FOR ALL METHODS OF CERVICAL RIPENING:

- **Informed consent for cervical ripening requires PCP discussion of associated risks including:**
  - Failure to establish labour
  - Tachysystole with or without fetal heart rate changes
  - Prolonged rupture of membranes and/or more frequent pelvic exams
  - Uterine rupture
  - Assisted vaginal birth or cesarean delivery
  - Postpartum hemorrhage
  - Adverse neonatal outcomes associated with iatrogenic preterm or early term birth
- **Contraindications for cervical ripening using prostaglandins:**
  - Lack of patient consent (absolute)
  - Abnormal fetal lie or presentation (e.g. transverse lie or footling breech) (absolute)
  - Active genital herpes (absolute)
  - Invasive cervical carcinoma (absolute)
  - Less than 36 weeks gestational age (absolute)
  - Pelvic structural deformities (absolute)
  - Placenta previa, vasa previa, invasive placentation, or cord presentation (absolute)
  - Prior uterine rupture, classical or inverted-T uterine incision, significant uterine surgery informed by a prior operative report (absolute)
  - Abnormal fetal heart rate (absolute)
  - Grand-multiparity: parity greater than or equal to 5 (relative)
  - Hydramnios (relative)
  - Breech presentation (relative)

- **Contraindications specific to cervical ripening with balloon catheters:**
  - Low-lying placenta (absolute)
  - Antepartum hemorrhage (relative)
  - Ruptured membranes (relative)
- **Prostaglandins are NEVER used simultaneously with other agents (oxytocin) that stimulate uterine contractions:**
  - A period of time must elapse after the administration of any prostaglandin agent when oxytocin induction or augmentation of labour is planned.
  - Cervidil® Vaginal insert: 30 minutes post removal must elapse.
  - Prostin® Vaginal gel: 6 hours must elapse.
  - Misoprostol Vaginal suppository: 4 hours must elapse
  - Misoprostol Oral Solution: 2 hours after last dose
- **Side Effects of Prostaglandins**
  - Nausea
  - Vomiting
  - Diarrhea
  - Abdominal pain
  - Shivering
  - Chills
  - Fever
- **Exclusion Criteria for Outpatient Use in Cervical Ripening:**
  - Less than 37 weeks or greater than 42 weeks gestation
  - Atypical/abnormal fetal heart rate pattern
  - Decreased amniotic fluid volume
  - Intrauterine growth restriction
  - Gestational hypertension severe enough to warrant inpatient monitoring
  - Intrauterine fetal demise
  - Patient lives greater than 30 minutes form hospital or does not have reliable transportation
  - Patient unable to understand instruction
  - PCP prefers inpatient care

PROCEDURE:

For all methods of cervical ripening:

1. An Induction Checklist is completed prior to the cervical ripening.
2. A 30-minute electronic fetal monitoring (EFM) tracing is reviewed and discussed with the PCP prior to cervical ripening.
3. Patient's vital signs are recorded in the medical record.
4. The PCP completes an in-person assessment prior to ordering cervical ripening to assess intervention appropriateness as well as review risk and benefits of the proposed treatment plan to ensure informed consent with the patient, see CLI.5810.PL.005.SD.04 Algorithm for Cervical Ripening and Induction of Labour. This discussion, and an order, are documented in the patient's medical record by the PCP.
5. The PCP administering the ordered intervention enters the following information in the Integrated Progress Note (IPN):
   - Indication for cervical ripening/induction/augmentation of labour.
   - Discussion that took place with the patient for risks and benefits of induction of labour.
   - Informed consent obtained from the patient by the PCP.
   - Description of the fetal heart rate (FHR) pattern.

- Description of the most recent cervical exam with modified Bishop score.
- Description of the fetal lie observed through Leopold's findings and/or point of care ultrasound findings.

6. After the administration of ripening agent, document the intervention performed and the time of administration.
7. Assess and document FHR as per the Intrapartum Fetal Health Surveillance provincial clinical guideline.
8. If tachysystole is present with an atypical/abnormal fetal heart rate pattern, follow CLI.5810.PL.005.SD.05 Intrauterine Resuscitation Techniques.
9. If cervical ripening is unsuccessful, the PCP considers an alternate or combined method of cervical ripening and/or induction of labour before proceeding with caesarean delivery.

Cervical Ripening Balloon (CRB)

A balloon catheter is a mechanical method of cervical ripening which results in direct pressure and overstretching of the lower segment and the cervix, and the local release of prostaglandins (Leduc, Biringer, Lee, & Dy, 2013). Types of balloon catheters include:

- 16, 18 or 20 French indwelling urinary catheters with a stated balloon capacity of 30 mL
- A double balloon cervical ripening catheter

Procedure:

1. Place the patient in a lithotomy position.
2. The PCP introduces the CRB under sterile technique into the transvaginal canal ensuring the bulb is above the internal os. This can be done by direct visualization (using a sterile speculum) or digitally.
3. Inflate the balloon with 30-60 mL of sterile water. With a double balloon catheter, the lower (vaginal) balloon is inflated also at the discretion of the PCP.
4. Tape the catheter hub to the inner thigh. Taping with tension is not required.
5. The inflation amount of the balloon(s) is documented in the IPN of the patient's medical record.
6. After insertion of the CRB, initiate continuous EFM including assessment of uterine activity, for a minimum of 20 minutes and document on the CLI.5810.FORM.042 Perinatal Triage Assessment form.
7. If the FHR pattern is normal as per the Intrapartum Fetal Health Surveillance provincial clinical guideline after 20 minutes, continuous EFM can be discontinued.
8. After one hour, the patient may be discharged home, with the CLI.5810.PL.005.SD.03 Going Home After Cervical Ripening handout, if they meet the following criteria:
    - Normal EFM tracing
    - Normal patient vital signs
    - PCP order
    - No exclusion criteria documented
9. If the patient remains in hospital following CRB insertion:
    - Assess uterine activity and Auscultate FHR every 4 hours
    - The patient may ambulate or shower after the initial 20-minute observation
    - The patient is instructed to inform nursing staff of the following:
        - Regular contractions
        - Symptoms consistent with spontaneous rupture of membranes
        - Vaginal bleeding
        - If the balloon falls out
    - Once in active labour, assess and document the FHR as per the Intrapartum Fetal Health Surveillance provincial clinical guideline.
    - The CRB is left in place until it spontaneously falls out or 24 hours has passed.

- CRB may be removed by the physician, resident, midwife or nurse (reference the IPN documented amount in balloon). Document time of removal in the IPN.

10. If PCP orders Oxytocin induction concurrently with CRB (MoreOB, 2023), see CLI.5810.PL.002 Induction and Augmentation of Labour. Patients remain in hospital, continuous EFM is performed as per the CLI.5810.SG.002 Fetal Health Surveillance (FHS) - Intrapartum and CLI.5810.PL.002 Induction and Augmentation of Labour.

Vaginal Misoprostol (PGE_1) Suppository for Cervical Ripening (prostaglandin E_1 (PGE_1))

Misoprostol (Cytotec®) is a synthetic prostaglandin E1 used for cervical ripening and has uterotonic effects. Serum levels peak 75 minutes after administration and clinical activity peaks at 2-3 hours, and the duration of action is 4-6 hours.

1. Vaginal misoprostol is administered by PCP.
2. The CLI.5810.PL.002.FORM.04 Misoprostol Safety Checklist is used prior to the administration of any misoprostol dose.
3. Administer a single 50 mcg suppository into the posterior fornix with minimal lubricant as medication is absorbed into the lubricant therefore decreasing its bioavailability.
4. Patient is encouraged to ambulate for 2 hours after administration.
5. Patients remain in hospital during vaginal misoprostol cervical ripening.
6. Auscultate FHR by intermittent auscultation hourly between EFM monitoring.
7. At 2 hours post-insertion, initiate continuous EFM and maintain for a minimum of 1 hour. Assess and record FHR and uterine activity every 15 minutes during this time.
8. May repeat Misoprostol vaginal suppository dose once, 6 hours after initial dose. Repeat monitoring as above if following criterial are met:
   - Modified bishop score **less** than 7
   - **No** uterine activity present
9. Once in active labour assess and document the FHR as per the Intrapartum Fetal Health Surveillance provincial clinical guideline.

Cervidil® (Dinoprostone 10 mg) Vaginal Insert (prostaglandin E_2 (PGE_2) mesh)

The 10mg pessary releases prostaglandin at a constant rate of 0.3 mg/hour and is inserted by the PCP into the posterior fornix of the vaginal canal.

1. After insertion of the Cervidil® initiate continuous EFM and assess uterine activity for a minimum of 20 minutes. Assess and record FHR and uterine activity every 10 minutes during this time on the CLI.5810.FORM.042 Perinatal Triage Assessment form.
2. The patient is advised to dab dry rather than wipe dry after voiding to prevent accidental removal of the Cervidil®.
3. If the Cervidil® falls out (i.e. protrudes beyond the labia) it may be reinserted. If the product is suspected to be soiled, notify the PCP to place a new Cervidil®.
4. Discharge patient home, with the CLI.5810.PL.005.SD.03 Going Home After Cervical Ripening handout, if they meet the following criteria:
   - Normal EFM strip
   - No signs of an acute hyperstimulation reaction
   - PCP order
   - No exclusion criteria documented
5. Give the patient the hospital number for the purpose of clarifying instructions only. Patients who have received interventions must return to the hospital for assessment and **are not triaged by telephone**.
6. Cervidil® may be removed by the patient if any adverse events are noted.

7. If the patient remains in hospital following Cervidil® insertion:
    - Auscultate FHR every hour. Additionally, initiate EFM every 4 hours for a minimum of 20 minutes and assess contractions while Cervidil® remains insitu.
    - The patient may ambulate or shower after the initial 20-minute observation
    - The patient is instructed to inform nursing staff of the following:
        - Regular or painful contractions
        - Symptoms consistent with spontaneous rupture of membranes
        - Vaginal bleeding
        - If the Cervidil® falls out
8. Cervidil® is removed for the following reasons:
    - Atypical/abnormal FHR pattern with or without tachysystole
    - At the discretion of the Nurse for tachysystole with a normal FHR pattern
    - Spontaneous rupture of membranes
    - Advanced active labour - greater than 6-7 cm
    - 18-24 hours post insertion
9. Once in active labour assess and document the FHR as per the Intrapartum Fetal Health Surveillance provincial clinical guideline.

Prostin® (Dinoprostone 2 mg/2.5mL) Gel (PGE_2 gel)

The clinical application of this PGE2 relates to its effect on uterine smooth muscle. It is absorbed from the vaginal vault and exerts a systemic effect on uterine musculature to initiate contractions. Repeat doses may be administered every 6-12 hours to a maximum of 3 doses.

1. Prostin® Gel is inserted by the PCP into the posterior fornix of the vagina. Prostin® duration of action is 4-6 hours.
2. After insertion of the Prostin® initiate continuous EFM and assess uterine activity for a minimum of 20 minutes. Assess and record FHR and uterine activity every 10 minutes during this time on the CLI.5810.FORM.042 Perinatal Triage Assessment form.
3. Discharge patient home, with the CLI.5810.PL.005.SD.01 Cervical Ripening Handout, if they meet the following criteria:
    - Normal EFM strip
    - No signs of an acute hyperstimulation reaction
    - Normal patient vital signs
    - PCP order
    - No exclusion criteria documented
4. If the patient remains in hospital following Prostin® insertion:
    - Auscultate FHR every hour. Additionally, initiate continuous EFM every 4 hours for a minimum of 20 minutes and assess contractions during Prostin® treatment.
    - The patient may ambulate or shower after the initial 20-minute observation
    - The patient is instructed to inform nursing staff of the following:
        - Regular or painful contractions
        - Symptoms consistent with spontaneous rupture of membranes
        - Vaginal bleeding
5. Once in active labour, assess and document the FHR as per the Intrapartum Fetal Health Surveillance provincial clinical guideline.

SUPPORTING DOCUMENTS:

CLI.5810.PL.005.SD.01	Cervical Ripening - Bilingual
CLI.5810.PL.005.SD.02	Cervical Ripening German
CLI.5810.PL.005.SD.03	Going Home after Cervical Ripening
CLI.5810.PL.005.SD.04	Algorithm for Cervical Ripening and Induction of Labour
CLI.5810.PL.005.SD.05	Intrauterine Resuscitation Techniques
CLI.5810.FORM.042	Perinatal Triage Assessment
CLI.5810.PL.002.FORM.01	Induction Checklist
CLI.5810.PL.002	Induction and Augmentation of Labour Guideline
CLI.5810.SG.002	Fetal Health Surveillance (FHS) - Intrapartum

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Robinson, d., Campbell, K, & Hobson, S., et al. 2023. "Guideline No. 432b: cervical ripening". Society of Obstetricians and Gynecologists of Canada (SOGC). 45(1): 56-62. https://doi.org/10.1016/j.jogc.2022.11.007.