

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### DRAFT COVERAGE GUIDANCE: INDICATIONS FOR PLANNED CESAREAN SECTION

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Planned cesarean section (CS) should be covered for:

- Breech presentation (if external cephalic version unsuccessful or contraindicated; and vaginal breech delivery is unavailable, undesired, or contraindicated)
- Twin pregnancy, if the presenting twin is not cephalic
- Partial or complete placenta previa
- Morbidly adherent placenta
- Human immunodeficiency virus (HIV) positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
- Primary herpes simplex virus infection in the third trimester

Planned CS should not be covered for:

- Twin pregnancy, if the presenting twin is cephalic
- Preterm birth
- Small for gestational age
- Suspected cephalopelvic disproportion
- Maternal Hepatitis B infection
- Maternal Hepatitis C infection
- Elective (without obstetrical or medical indication)

For the following conditions, an individualized treatment plan taking into account maternal and infant health should be developed to determine if planned CS versus planned vaginal delivery are the appropriate route of delivery.

- Herpes simplex virus recurrence at birth
- Body mass index over 50
- Prior CS delivery
- HIV positive mothers on highly active anti-retroviral therapy with a viral load less than 400 copies/ml, or on any anti-retroviral therapy with a viral load of less than 50 copies/ml

## RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

## EVIDENCE SOURCES

Cunningham, F.G., Bangdiwala, S., Brown, S.S., Dean, T.M., Frederiksen, M., Rowland Hogue, C.J., et al. (2010). National Institutes of Health Consensus Development Conference Statement: Vaginal birth after cesarean: New insights. March 8-10, 2010. *Obstetrics & Gynecology*, 115(6), 1279–1295. Retrieved from [http://consensus.nih.gov/2010/images/vbac/vbac\\_statement.pdf](http://consensus.nih.gov/2010/images/vbac/vbac_statement.pdf)

Guise, J-M., Eden, K., Emeis, C., Denman, M.A., Marshall, N., Fu, R, et al. (2010). *Vaginal birth after cesarean: New insights. Evidence Report/Technology Assessment No.191. (Prepared by the Oregon Health & Science University Evidence-based Practice Center under Contract No. 290-2007-10057-I). AHRQ Publication No. 10-E003.* Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from <http://www.ncbi.nlm.nih.gov/books/NBK44571/>

National Institute for Health and Clinical Excellence, & National Collaborating Centre for Women's and Children's Health. (2011). *Caesarean section. (Clinical guideline 132).* London, UK: Royal College of Obstetricians and Gynaecologists Press. Retrieved from <http://guidance.nice.org.uk/CG132>

NIH State-of-the-Science Conference Statement on Cesarean Delivery on Maternal Request. *NIH Consens Sci Statements*. 2006. Mar 27-29; 23(1) 1–29. Retrieved from <http://consensus.nih.gov/2006/cesareanstatement.pdf>

Risser, A., & King, V. (2010). *Rapid review: Elective cesarean section.* Portland: Center for Evidence-based Policy. Retrieved from <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Elective-Delivery-Elective-Cesarean PUBLIC Rapid-Review Final 12 1 10.pdf>

## SUMMARY OF EVIDENCE

### **Clinical Background**

According to the National Center for Health Statistics, the national rate of CS reached 32.8 percent of all live births in 2010. The largest contributions to this rising rate are an increase in primary cesareans to a rate of 20.6 percent in 2004 and a steep decline in the rate of vaginal birth after cesarean (VBAC) from 28.3% in 1996 to 9.2% in 2004. Over ninety percent of women who have had a CS will deliver by repeat cesarean. This increase is not well explained by changes in the population risk profile. There is interest in understanding the factors underlying this increase and to understand to what extent primary planned CS done without an identifiable medical risk (elective CS) and CS by maternal request contribute to this rate. The best estimate is that between 4% and 18% of primary CS in the United States are elective.

## Evidence Review

### Elective Cesarean Delivery

The literature pertaining to the benefits and harms of cesarean delivery is limited by the lack of randomized trials that compare mode of *intended* delivery. Nearly all of the evidence compares outcomes based on actual delivery mode rather than intended mode of delivery, limiting the conclusions that can be drawn.

The MED report concluded that although much of the evidence is of low quality, the following outcomes are likely associated with elective CS:

- longer hospital stays;
- increased Neonatal Intensive Care Unit (NICU) admissions;
- increased neonatal respiratory problems; and
- maternal urinary or fecal incontinence is less likely in the short term, with no difference in longer term follow up.

The differences between an intended vaginal delivery group and an intended cesarean group are less marked for these outcomes at 39 or more weeks of gestation. Elective cesarean delivery likely has no benefit for urinary or fecal continence in the longer term, although immediate postpartum outcomes may favor elective CS. There are important downstream effects to consider in the performance of elective CS, most notably in maternal morbidity due to abnormal placentation. There are some important issues around quality of life such as post partum pain, recovery time, and postpartum mood which are important, but which have not been well studied as they apply to elective CS.

The 2010 MED report draws heavily from the AHRQ systematic review that was commissioned to inform the 2006 National Institute of Health (NIH) State of the Science Consensus Statement on Cesarean Delivery on Maternal Request, as well as the AHRQ review commissioned to inform the 2010 NIH Consensus Development Conference on Vaginal Birth after Cesarean: New Insights. The 2006 NIH consensus statement draws the following conclusions:

- There is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed.
- Until quality evidence becomes available, any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles.
- Given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children.

- Cesarean delivery on maternal request should not be performed prior to 39 weeks of gestation because of the significant danger of neonatal respiratory complications.
- Maternal request for cesarean delivery should not be motivated by unavailability of effective pain management. Efforts must be made to assure availability of pain management services for all women.

The majority of planned CS in the United States are performed for women who have a prior history of cesarean birth. The 2010 AHRQ systematic review *Vaginal Birth after Cesarean: New Insights* concluded the following:

“Each year 1.5 million childbearing women have cesarean deliveries, and this population continues to increase. This report adds stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean. Moreover, there is emerging evidence of serious harms relating to multiple cesareans. Relatively unexamined contextual factors such as medical liability, economics, hospital structure, and staffing may need to be addressed to prioritize VBAC services. There is still no evidence to inform patients, clinicians, or policy-makers about the outcomes of *intended* route of delivery because the evidence is based largely on the actual route of delivery. This inception cohort is the equivalent of intention to treat for randomized controlled trials and this gap in information is critical.”

This AHRQ systematic review contributed to the evidence presented to a NIH Consensus Conference. The 2010 NIH Consensus Development Conference on *Vaginal Birth after Cesarean: New Insights* found the following:

*Maternal Benefits of a trial of labor*

- Women who have a trial of labor, regardless of ultimate mode of delivery, are at decreased risk of maternal mortality compared to elective repeat cesarean delivery. (Evidence grade: high)
- There is an association between cesarean delivery and abnormal placental position and growth in subsequent pregnancies and the risk of having abnormal placental position and growth increases with increasing number of cesarean deliveries. Overall, the major benefit of trial of labor is the 74 percent likelihood of VBAC and avoidance of multiple cesarean deliveries. The following health outcomes occur less frequently in women who have a VBAC (i.e. a successful trial of labor) (Evidence grade: moderate):
  - The incidence of placenta previa (placenta covering the cervix) significantly increases in women with each additional cesarean delivery
  - The incidence of placenta accreta, increta, and percreta (growth of the placenta into or through the uterine muscle) increases with the number of cesarean deliveries.

- There does not appear to be an increased incidence of placental abruption (i.e., premature separation of the normally implanted placenta from the uterus) with increasing number of cesarean deliveries, although the risk is increased when women who have one prior cesarean delivery are compared to women who have not had a cesarean delivery.
- The overall risk of hysterectomy is statistically similar for trial of labor compared with elective repeat cesarean delivery (157 versus 280 per 100,000 respectively) and may be less in women at term. Limited evidence suggests that the risk of hysterectomy increases with induction of labor, high-risk pregnancy, and increasing number of cesarean deliveries (Evidence grade: moderate)
- The risk of blood transfusion is not significantly different for trial of labor or elective repeat cesarean delivery (900 versus 1,200 per 100,000). Factors that increase this risk include induction of labor with no prior vaginal delivery, high-risk pregnancy, and an increased number of prior cesarean deliveries.(Evidence grade: moderate)
- There is shorter hospitalization overall for trial of labor compared to elective repeat cesarean delivery. This benefit does not pertain to morbidly obese women. A single study suggests lower rates of deep venous thrombosis (DVT) in women undergoing trial of labor compared with elective repeat cesarean delivery (Evidence grade: low)

#### *Maternal Harms of a trial of labor*

- There is a clear increased risk of uterine rupture in women who have a trial of labor compared to elective repeat cesarean delivery. (Evidence grade: Moderate). Low grade evidence finds the following:
  - Women with classical and low vertical uterine scars have an increased risk of rupture when compared to women who had a low transverse uterine incision
  - Induction of labor has been associated with uterine rupture.
  - Increasing number of prior cesarean deliveries may increase risks of uterine rupture
  - A prior vaginal birth (before or after the previous cesarean delivery) decreases the risk of uterine rupture to approximately
- The evidence is insufficient to address a woman's perceptions of her birth experience, initial parent-infant interactions, ability to perform activities of daily living or initiate breastfeeding, association with other conditions such as chronic pain, ectopic pregnancy, stillbirth, infertility, complications related to subsequent surgery, pelvic floor function, rates of infection or surgical injury.

### *Neonatal effects of a trial of labor*

- Studies of perinatal mortality (death between 20 weeks of gestation and 28 days of life) are of moderate quality and show that the perinatal mortality rate is increased for trial of labor (Evidence grade: moderate)
- Studies of fetal mortality (deaths in utero at 20 weeks of gestation or greater) suggest a higher death rate in trial of labor (Evidence grade: low)
- The evidence on hypoxic ischemic encephalopathy is unclear. The NIH Consensus Conference, noting a recent large observational study that found a significantly higher incidence of hypoxic ischemic encephalopathy in trial of labor compared with elective repeat cesarean delivery, rated the evidence grade on this finding as low, while the AHRQ SR rated it as insufficient.
- The evidence is insufficient to address respiratory sequelae, sepsis, birth trauma, breastfeeding and mother-infant bonding.

### Indications for Cesarean Section

The 2010 MED report relied on the guideline and systematic review conducted by the National Institute for Clinical Excellence (NICE) published in 2004 to determine the indications for planned cesarean section, but noted that this guideline would be updated in 2011. The updated guideline was published in November 2011 (<http://www.nice.org.uk/nicemedia/live/13620/57162/57162.pdf>). The 2011 NICE guideline identified one small study (N= 357), published after the 2004 guideline, that compared primiparous women planning a CS in the absence of medical indication to those planning a vaginal birth. That study found the following outcomes in the planned CS group:

- Longer maternal hospital stays
- Better “birth experience” at 2 days and 3 months
- Worse “uncomplicated breast feeding” at 3 months
- Lower likelihood of plans for another child at 3 months

There were no statistically significant differences between groups in the following outcomes:

- Resumption of coitus at 3 months
- Depression
- NICU care

The quality of the evidence was rated very low, however, the guideline authors recommend that “For women requesting a CS, if after discussion and offer of support (including perinatal mental health support for women with anxiety about childbirth), a vaginal birth is still not an acceptable option, offer a planned CS. “

## Indications for Cesarean Delivery

The 2011 NICE guideline recommends planned CS for the following indications:

- Breech presentation (if external cephalic version unsuccessful or contraindicated)
- Twin pregnancy, if the presenting twin is not cephalic
- Partial or complete placenta previa
- Morbidly adherent placenta
- HIV positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
- Primary herpes simplex virus infection in the third trimester

The 2011 NICE guideline does not recommend planned cesarean, either because of insufficient evidence, or because there is a balance of trade offs between clinical benefits and harms or net health benefits and resource use, for the following indications:

- Twin pregnancy, if the presenting twin is cephalic
- Preterm birth
- Small for gestational age
- Suspected cephalopelvic disproportion
- HIV positive mothers on highly active anti-retroviral therapy with a viral load less than 400 copies/ml, or on any anti-retroviral therapy with a viral load of less than 50 copies/ml
- Maternal Hepatitis B infection
- Maternal Hepatitis C infection
- HSV recurrence at birth
- Body mass index over 50
- Prior CS delivery

## **Recommendations from Others**

The American College of Obstetrics and Gynecology (ACOG) does not list specific indications for cesarean section, but some of their documents suggest when it is appropriate. When a guideline or bulletin exists, their recommendations do not contradict the NICE recommendations presented above, with two exceptions. For women with herpes simplex virus who have active genital lesions or prodromal symptoms, ACOG recommends CS. In addition, they state that CS should be

considered for obese women with an estimated fetal weight of more than 5000 grams, or more than 4500 grams for obese patients with diabetes.

## **Overall Summary**

Elective CS is likely associated with longer hospital stays, increased NICU admissions and increased neonatal respiratory problems. While maternal urinary or fecal incontinence is less likely in the short term, there is no difference in longer term follow up. A 2006 NIH consensus statement concludes that there is insufficient evidence to fully evaluate the benefits and risks of cesarean delivery on maternal request, and given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children. The majority of planned CS in the US are performed for women who have a prior history of Cesarean birth. A 2010 AHRQ systematic review reports stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean, and that there is emerging evidence of serious harms relating to multiple cesareans. The 2011 NICE guideline recommends planned CS only for breech presentation, twin pregnancy (if the presenting twin is not cephalic), placenta previa and accreta, HIV positive mothers in some circumstances and primary herpes simplex virus infection in the third trimester. These indications are supported by ACOG, and in addition, ACOG considers obesity with high estimated fetal weight and HSV recurrence at birth additional indications for planned CS. For all other indications, the evidence is insufficient to recommend cesarean section. Planned cesareans without an evidence-based indication may increase neonatal and maternal harms, increase costs, and result in unnecessary procedures.

## PROCEDURE

Cesarean Section

## DIAGNOSES

Pregnancy

## APPLICABLE CODES

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD 9 Codes</b>	
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
<b>ICD 9 Volume 3 (procedure codes)</b>	
74.0	Classical cesarean section
74.1	Low cervical caesarean section
74.4	Cesarean section of other specified type
<b>ICD 10 Codes</b>	
O82	Single delivery by caesarean section
O82.0	Delivery by elective caesarean section
O82.2	Delivery by caesarean hysterectomy
O82.8	Other single delivery by caesarean section
O82.9	Delivery by caesarean section, unspecified
<b>CPT Codes</b>	
Elective Cesarean	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care
Nonelective Cesarean	
59618	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
Vaginal Delivery	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409,	Vaginal delivery only, with and without postpartum care

59410	
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612, 59614	Vaginal delivery only, after previous cesarean delivery; with or without postpartum care
<b>HCPCS Codes</b>	
None	

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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