



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Amnioinfusion**

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## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

CIGNA covers amnioinfusion as medically necessary for EITHER of the following indications:

- treatment or prevention of complications caused by oligohydramnios
- reduction of severe variable fetal heart rate deceleration during labor

**CIGNA does not cover amnioinfusion for the prevention of meconium aspiration syndrome (MAS) caused by meconium-stained amniotic fluid (MSAF) or any other indication because it is considered experimental, investigational or unproven.**

## General Background

Amnioinfusion is the instillation of normal saline or lactated Ringer's solution into the amniotic sac to correct oligohydramnios (i.e., a reduction of amniotic fluid volume), alleviate variable decelerations, dilute thick meconium and improve the intrauterine environment. It has been proposed that by artificially increasing the volume of amniotic fluid, amnioinfusion better protects the umbilical cord from compression, thereby reducing the number and severity of variable decelerations. It has also been proposed that diluting thick, meconium-stained fluid reduces the risk of meconium aspiration and subsequent complications (Gelfand, et al., 2004). Amnioinfusion can be performed transabdominally or transcervically. Intrauterine pressure should be continuously monitored during this procedure. Although generally considered safe, reported complications

associated with amnioinfusion include uterine rupture, placental abruption, and chorioamnionitis (American College of Obstetricians and Gynecologists [ACOG], 2006). It is usually performed in critical situations, where the benefits of the procedure outweigh the risks. Contraindications for amnioinfusion include multiple gestation, chorioamnionitis, undiagnosed third-trimester bleeding, and fetal malpresentation.

Oligohydramnios can occur during any stage of pregnancy. An amniotic fluid index (AFI) of < 5 cm is indicative of oligohydramnios. Causes of oligohydramnios include premature rupture of membranes (PROM), post-maturity (i.e., more than 42 weeks' gestation), and maternal health problems such as hypertension (National Institute for Health and Clinical Excellence [NICE], 2006). When the condition occurs in the first half of pregnancy, it increases the risk of birth defects, miscarriage and preterm birth. Oligohydramnios in the second half of pregnancy may cause poor fetal growth. Near term, it has been associated with complications of labor and delivery, including meconium-stained amniotic fluid (MSAF), umbilical cord compression, and variable decelerations. Women with oligohydramnios are more likely than unaffected women to require cesarean deliveries.

Meconium aspiration syndrome (MAS) is believed to result from aspiration of meconium during intrauterine gasping or at the first breath. The syndrome is characterized by the development of respiratory distress in an infant born through MSAF whose symptoms cannot otherwise be explained. Treatment strategies for MAS include deep suctioning of the nasal passages and hypopharynx during delivery and immediate tracheal suctioning and airway support after birth. While it has been proven that amnioinfusion reduces the consistency of meconium, it is less clear whether amnioinfusion prevents MAS.

### Literature Review

**Oligohydramnios/PROM:** The evidence in the published peer-reviewed literature evaluating the effectiveness of intrapartum prophylactic amnioinfusion for oligohydramnios includes a systematic review, meta-analyses, and a number of randomized controlled trials (RCTs) dating back to the 1990s. Additional evidence supporting the use of amnioinfusion for oligohydramnios includes a case-control study (n=100) by Chhabra et al. (2007). There was a statistically significant difference in the perinatal mortality rate for amnioinfusion patients (n=50) compared with controls who received conservative treatment (p<0.001).

A guidance issued by the National Institute for Health and Clinical Excellence (NICE) on the use of therapeutic amnioinfusion for oligohydramnios states that the "current evidence on the safety and efficacy of therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labor) does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. Most of the evidence on the procedure relates to preterm premature rupture of membranes, rather than other causes of oligohydramnios. Therapeutic amnioinfusion for oligohydramnios during pregnancy should only be performed in centers specializing in invasive fetal medicine and in the context of a multidisciplinary team, which may include a consultant in fetal medicine, a neonatologist and a specialist midwife" (NICE, 2006).

A Cochrane review (n=2 RCTs; 285 subjects) and meta-analysis by Hofmeyr (2000a) found no benefit for administering amnioinfusion prophylactically for oligohydramnios compared to withholding the procedure until FHR decelerations or meconium-staining of the amniotic fluid occurred. Another meta-analysis by Pitt et al. (2000) (n=14 RCTs; 1533 subjects) reported that compared to the women in the control group (n=740), those who received amnioinfusion (n=793) had lower cesarean rates for FHR abnormalities during labor and for acidemia at birth. Postpartum endometritis rates were found to be similar among the study groups.

RCTs have evaluated the role of transabdominal amnioinfusion in improving the perinatal outcomes of pregnancies complicated by preterm PROM (pPROM), a significant causative factor for oligohydramnios. An RCT by Singla et al. (2010) reported outcomes for a group of women whose amniotic fluid index (AFI) was less than the 5th percentile and who underwent either an amnioinfusion protocol (n=30) or expectant management (n=30). Neonatal and maternal outcomes, including fetal distress (p=0.03) and neonatal mortality (p<0.01) were found to be significantly improved in the study group compared with the control group.

An RCT (n=86) by Puertas et al. (2006) found that there was a greater reduction in frequency of variable decelerations in FHR for those who received amnioinfusion compared to patients who had conventional medical management (p<0.05). Results from an RCT (n=34) by Tranquilli et al. (2005) indicated that the period of time from onset of pPROM to delivery was significantly longer in women who underwent amnioinfusion versus those

who received expectant management only ( $p < 0.05$ ). Also, neonatal survival was reported to be significantly higher at each gestational age ( $p < 0.01$ ) in the amnioinfusion group.

There is sufficient evidence in the published peer-reviewed medical literature to support the use of amnioinfusion for oligohydramnios and PROM. The procedure has been proven to be more effective for reducing complications resulting from decreased intra-amniotic volume than standard expectant management.

#### **Fetal Heart Rate (FHR) Decelerations:**

Studies evaluating the effectiveness of amnioinfusion for reducing the rate of recurrent variable decelerations include RCTs, primarily conducted in the 1990s, and a meta-analysis. An RCT by Regi et al. (2009) found significant relief of variable decelerations and significant reduction in cesarean section rate for fetal distress in a group of women who received amnioinfusion ( $n=75$ ) compared with those who had conservative medical management ( $n=75$ ). Neonatal acidemia was also found to be significantly reduced in the nulliparous women receiving amnioinfusion.

A Cochrane meta-analysis ( $n=12$  RCTs) by Hofmeyr (2000b) assessed the effects of amnioinfusion for potential or suspected umbilical cord compression or potential amnionitis on maternal and perinatal outcomes. Both transcervical and transabdominal amnioinfusion were found to be associated with reductions in fetal heart rate decelerations and cesarean section for suspected fetal distress. The trials reviewed are too small to address the possibility of rare but serious maternal adverse effects of amnioinfusion.

The published peer-reviewed medical literature contains some evidence to suggest that amnioinfusion safely and effectively reduces variable FHR decelerations and thereby improves neonatal outcomes as compared to conservative medical management.

**MSAF/MAS:** The effectiveness of intrapartum prophylactic amnioinfusion in pregnancies complicated by MSAF has been examined in RCTs, systematic reviews and meta-analyses. Study results have been conflicting with some evidence showing a benefit of the use of amnioinfusion in pregnancies complicated by MSAF together with oligohydramnios. An RCT ( $n=292$ ) by Choudhary et al. (2010) evaluate the safety and efficacy of intrapartum amnioinfusion complicated by MSAF. Outcomes included the incidence of caesarean sections, MAS and perinatal mortality. A statistically significant reduction in the incidence of cesarean sections was found in the amnioinfusion group compared to the control group ( $p=0.000$ ). There was also a statistically significant difference in the occurrence of MAS and perinatal mortality in favor of the amnioinfusion group.

The results of a systematic review and meta-analysis of 12 studies ( $n=4030$ ) by Xu et al. (2007) review indicated that, in clinical settings with standard peripartum surveillance, amnioinfusion does not reduce the risk of MAS. However, in settings with limited peripartum surveillance, amnioinfusion appeared to reduce the risk of MAS. Another meta-analysis, Hofmeyr (2002) found amnioinfusion to be associated with a reduction in heavy MSAF, variable fetal heart rate deceleration and overall cesarean section rate in clinical settings with or without electronic fetal monitoring. It was noted that the reduction in the incidence of MAS after amnioinfusion seen in these studies may possibly be due to a reduction in fetal distress related to oligohydramnios. A meta-analysis of 13 prospective RCTs ( $n=1924$ ) by Pierce et al. (2000) identified a significant decrease in the incidence of MAS with amnioinfusion ( $n=950$ ) compared to controls ( $n=974$ ). The incidence of fetal acidemia at birth, as well as the overall cesarean delivery rate, was also found to be significantly lower in the amnioinfusion group.

Other study results have indicated that amnioinfusion does not result in a greater reduction in neonatal mortality or the risk of meconium aspiration than standard peripartum surveillance. A large, international, multicenter trial ( $n=1998$ ) by Fraser et al. (2005), randomized women in labor at 36 weeks of gestation or later with thick MSAF to amnioinfusion or standard care. Perinatal death and/or MAS occurred in 44 infants (4.5%) of women in the amnioinfusion group ( $n=995$ ) and 35 infants (3.5%) of women in the control group ( $n=1003$ ). An equal number ( $n=5$ ) of perinatal deaths occurred in each group. The cesarean delivery rate was also similar for the amnioinfusion and control groups.

The evidence in the published peer-reviewed medical literature has not consistently demonstrated that the use of amnioinfusion for MSAF prevents MAS and leads to improved perinatal outcomes such as the reduction of cesarean procedures and neonatal mortality.

## Professional Societies/Organizations

The March of Dimes states that oligohydramnios occurring in the first two trimesters of pregnancy is more likely to cause serious problems than if it occurs in the last trimester. Problems associated with early oligohydramnios include miscarriage, birth defects, and premature birth. Oligohydramnios in the third trimester may be associated with poor fetal growth, complications of labor and delivery, including compression of the umbilical cord, and increased risk of cesarean birth. If a woman has severe oligohydramnios near the time of delivery, and the baby shows signs of cord compression, the physician may suggest amnioinfusion to help reduce complications during labor and delivery and reduce the need for cesarean section (March of Dimes, 2010).

The Institute for Clinical Systems Improvement (ICSI) guideline for the management of labor states that indications for therapeutic amnioinfusion include repetitive severe variable decelerations and prolonged decelerations. ICSI also recommends that the use of amnioinfusion be considered for oligohydramnios. However, amnioinfusion for thick meconium is no longer recommended (ICSI, 2009).

According to the American College of Obstetricians and Gynecologists (ACOG) on the intrapartum monitoring of fetal heart rate, amnioinfusion to relieve umbilical cord compression should be considered when the FHR tracing includes recurrent variable decelerations (ACOG, 2009).

The ACOG committee opinion on amnioinfusion for MAS states that the purported benefit of amnioinfusion for the dilution of MSAF is dilution of thick clumps of meconium. However, a large proportion of women with MSAF have infants who have aspirated meconium before meconium passage has been noted and before amnioinfusion can be performed. Also, in many cases, MAS is hypothesized to predate labor. According to ACOG, based on current literature, routine prophylactic amnioinfusion for MSAF is not recommended. Prophylactic use of amnioinfusion for MSAF should be done only in the setting of additional clinical trials (ACOG, 2006).

The World Health Organization (WHO) states that amnioinfusion during labor for treatment of cord compression is effective in correcting FHR abnormalities, Apgar scores, birth asphyxia and lowering caesarean section rates if the indication for caesarean section is based on FHR criteria alone. Amnioinfusion during labor when moderate or thick meconium is noted is also effective in reducing the incidence of meconium found below the vocal cords, MAS and caesarean section rate, but the safety of amnioinfusion concerning rare but serious maternal complications is not established. The effectiveness of amnioinfusion for moderate or thick meconium staining during labor in terms of reduction of perinatal mortality due to meconium aspiration is also unknown (WHO, 2002).

## Summary

The overall body of evidence in the published, peer-reviewed literature indicates that amnioinfusion is safe and effective when used to treat the complications of oligohydramnios. The evidence regarding prophylactic versus therapeutic use of amnioinfusion for oligohydramnios is inconsistent. There is some limited evidence to suggest that prophylactic amnioinfusion may be warranted in pregnancies with premature rupture of membranes (PROM), where there is an increased risk for the development of variable decelerations due to oligohydramnios.

Controversy also exists as to the effectiveness of amnioinfusion used specifically for the prevention of meconium aspiration syndrome (MAS). Based on the current evidence in the published scientific literature and professional society recommendation, the use of amnioinfusion for this indication is not supported.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®</sup> * Codes	Description
59070	Transabdominal amnioinfusion, including ultrasound guidance

ICD-9-CM Diagnosis Codes	Description
658.00	Oligohydramnios, unspecified as to episode of care or not applicable
658.01	Oligohydramnios, with or without mention of antepartum condition
658.03	Oligohydramnios, antepartum condition or complication
659.70	Abnormality in fetal heart rate or rhythm, unspecified as to episode of care or not applicable
659.71	Abnormality in fetal heart rate or rhythm, delivered, with or without mention of antepartum condition
659.73	Abnormality in fetal heart rate or rhythm, antepartum condition or complication
761.2	Fetus or newborn affected by oligohydramnios
762.5	Fetus or newborn affected by other compression of umbilical cord
763.81 – 763.83	Abnormality in fetal heart rate or rhythm

**Experimental/Investigational/Unproven/Not Covered:**

ICD-9-CM Diagnosis Codes	Description
770.11	Meconium aspiration without respiratory symptoms, of fetus and newborn
770.12	Meconium aspiration with respiratory symptoms, of fetus and newborn
779.84	Meconium staining
	All other codes

\*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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## Policy History

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<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	11/15/2006	0222	Amnioinfusion

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