



# CIGNA MEDICAL COVERAGE POLICY

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

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Coverage Policy Number .....0222

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 as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant'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 participant'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 participant'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 group 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. Proprietary information of CIGNA. Copyright ©2008 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) because it is considered experimental, investigational or unproven for this indication.**

## 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. 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.

Approximately 13% of all live births are complicated by MSAF. Meconium aspiration syndrome (MAS) occurs in 5% of neonates born through MSAF. 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:** In a Cochrane review, Hofmeyr (2000) assessed the effects of prophylactic amnioinfusion for oligohydramnios compared with therapeutic amnioinfusion only if fetal heart rate decelerations or thick meconium-staining of the liquor occurred. The review included two randomized trials (n=285) that compared prophylactic with therapeutic amnioinfusion administered to women in labor with oligohydramnios but without fetal heart rate deceleration. No differences were found in the rate of caesarean section (relative risk 0.98, 95% confidence interval 0.58 to 1.66), or forceps delivery. There were also no differences found in outcomes that included Apgar scores, cord arterial pH, meconium aspiration, or neonatal pneumonia. According to the author, the results indicated that there was no benefit for administering amnioinfusion prophylactically compared to withholding the procedure until fetal heart rate (FHR) decelerations or meconium-staining of the amniotic fluid occurred.

The effectiveness of intrapartum prophylactic amnioinfusion in pregnancies complicated by oligohydramnios was evaluated in a metaanalysis of 14 randomized, controlled trials (RCTs) (n=1533). There were 793 in the amnioinfusion group, and 740 controls. The trials were evaluated concerning cesarean deliveries for fetal heart rate (FHR) abnormalities, overall cesarean rates, acidemia at birth, intrapartum fetal heart rate abnormalities, Apgar scores under 7 at 5 minutes, and postpartum endometritis. Compared to the women in the control group, those who received amnioinfusion 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 (Pitt, et al., 2000).

The National Institute for Health and Clinical Excellence (NICE) has published a guidance on the use of therapeutic amnioinfusion for oligohydramnios. The NICE guidance 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).

Chhabra et al. (2007) conducted a case-control study of 100 pregnant women with oligohydramnios, who received amnioinfusion (n=50) or conservative treatment (n=50). The controls were matched for age, parity, and pregnancy duration with the case patients. There was a mean 4.02 cm increase in amniotic fluid index (AFI) after amnioinfusion. The mean interval between admission and delivery was 7.4 days for controls and 18.44 days for case patients. Of the 50 women in the treatment group, 18% required cesarean sections compared to 46% of controls. Fetal distress was responsible for cesarean section in 61.5% of the case patients and 82.6% of

the controls ( $p < 0.05$ ). The perinatal mortality rate was 4% for amnioinfusion patients, and 18% among controls ( $p < 0.001$ ). The authors noted that because antepartum amnioinfusion is invasive and carries some risks, it warrants proper selection of patients. However, the procedure may be useful for reducing complications resulting from decreased intra-amniotic volume (Chhabra, et al., 2007).

**PROM:** Tranquilli et al. (2005) conducted an RCT to evaluate the role of transabdominal amnioinfusion in improving the perinatal outcomes of pregnancies complicated by preterm PROM (pPROM). Women with singleton pregnancies between 24 and 32 + 6 weeks of gestation were randomized to expectant management with transabdominal amnioinfusion ( $n=17$ ) or expectant management only ( $n=17$ ). Outcome measures included the effects of transabdominal amnioinfusion on pPROM-delivery interval and on perinatal outcomes. Results indicated that the period of time from onset of pPROM to delivery was significantly longer in women who underwent amnioinfusion (i.e., median: 21 days; range: 15 to 29) ( $p < 0.05$ ). Neonatal survival was reported to be significantly higher at each gestational age ( $p < 0.01$ ) in the amnioinfusion group. It was concluded that treatment with transabdominal amnioinfusion after pPROM resulted in significant prolongation of pregnancy and better neonatal outcomes compared with standard expectant management (Tranquilli, et al., 2005).

Puertas and colleagues (2006) assessed the effect of transcervical amnioinfusion on the management of labor and neonatal outcomes in pPROM. This RCT included women with pregnancies between 27 and 35 weeks' gestation who were randomly assigned to receive either expectant management ( $n=43$ ) or amnioinfusion ( $n=43$ ). Amnioinfusion was reported to reduce the frequency of variable decelerations in FHR at a significantly higher rate than conventional medical management ( $p < 0.05$ ). The rate of obstetric interventions caused by nonreassuring fetal status was found to be lower in the amnioinfusion group (13.6%) compared with the control group (52.4%). At delivery, pH values were found to be significantly higher in the treatment group than in the control group (median 7.29 versus 7.27). The authors concluded that intrapartum transcervical amnioinfusion for pPROM reduced the number of interventions needed because of nonreassuring fetal status, and improved neonatal acid-base balance without increasing maternal or fetal morbidity (Puertas, et al., 2006).

**MSAF/MAS:** Pierce et al. (2000) evaluated the effectiveness of intrapartum prophylactic amnioinfusion in pregnancies complicated by MSAF in a metaanalysis. A total of 13 prospective RCTs met inclusion criteria for this systematic review. It was noted by the authors that studies have had small sample sizes and, therefore, difficulty showing significant differences due to the rarity of MAS. A combined total of 1924 women were enrolled in the trials. Pooled data 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.

In another metaanalysis, Hofmeyr (2002) reviewed 12 RCTs to assess the effects of amnioinfusion for MSAF on perinatal outcomes. Amnioinfusion was found 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. The author 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. It has not been determined whether amnioinfusion improves the outcome of pregnancies with MSAF unrelated to the correction of oligohydramnios. The evidence does show a benefit of the use of amnioinfusion in pregnancies complicated by MSAF together with oligohydramnios (Hofmeyr, 2002).

Fraser et al. (2005) conducted a multi-center RCT to determine whether amnioinfusion reduces the risk of perinatal death, moderate or severe meconium aspiration, or both. Electronic fetal monitoring and neonatal resuscitation measures were available in all participating centers. A total of 1998 women were randomly assigned to receive either amnioinfusion or standard care. The composite outcome of 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 (five) of perinatal deaths occurred in each group. The cesarean delivery rate was 31.8% in the amnioinfusion group and 29.0% for controls. Based on these results, it was concluded that amnioinfusion should not be recommended for the prevention of MAS in clinical settings with "standard peripartum surveillance." The authors noted that the results of this study can only be generalized to similar clinical settings (Fraser, et al., 2005).

Xu et al (2007) performed a systematic review to assess the effectiveness of amnioinfusion in reducing MAS and other indicators of morbidity in babies born to women with MSAF. Studies were retained if they were RCTs that evaluated the effect of prophylactic amnioinfusion during labor and women were randomly assigned to

amnioinfusion versus control exclusively in the presence of MSAF during labor. A total of 12 studies (n=4030) were included in the main meta-analysis. Of the 4030 women, 1999 received amnioinfusion and 2031 served as a control. Of the 12 trials, two were conducted in settings with limited peripartum surveillance where electronic fetal heart monitoring was not routinely available. Results of the systematic 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. It was noted that additional studies are needed to confirm the latter finding.

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, 2007).

### **Professional Societies/Organizations**

According to the World Health Organization (WHO), 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 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).

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 March of Dimes states that when oligohydramnios occurs in the second half of pregnancy, it may be associated with poor fetal growth. Near term, oligohydramnios may increase the risk of complications of labor and delivery, including compression of the umbilical cord. Women with oligohydramnios are more likely than unaffected women to need a cesarean section. If a woman has severe oligohydramnios near the time of delivery, her physician may suggest amnioinfusion to help reduce complications during labor and delivery and reduce the need for cesarean section (March of Dimes, 2007).

### **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. Additional randomized, controlled studies are needed to confirm the benefit of prophylactic amnioinfusion in routine clinical practice.

Controversy also exists as to the effectiveness of amnioinfusion used specifically for the prevention of meconium aspiration syndrome (MAS). However, based on the current evidence in the published scientific literature and professional society recommendation, the use of amnioinfusion for this indication is no longer supported.

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## **Coding/Billing Information**

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

**Covered when medically necessary:**

CPT®*	Description
59070	Transabdominal amnioinfusion, including ultrasound guidance

ICD-9-CM Diagnosis Codes	Description
656.80	Other specified fetal and placental problems affecting management of mother, unspecified as to episode of care
656.81	Other specified fetal and placental problems affecting management of mother, delivered
656.83	Other specified fetal and placental problems affecting management of mother, antepartum
658.00 – 658.03	Oligohydramnios without mention of rupture of membranes
658.10 – 658.13	Premature rupture of membranes in pregnancy
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

\*Current Procedural Terminology (CPT®) © 2007 American Medical Association: Chicago, IL.

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## Policy History

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

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.