# Fetal surgeries in utero

Clinical Policy ID: CCP.1004

Recent review date: 2/2022

Next review date: 6/2023

Policy contains: congenital cystic adenomatoid malformation and fetal hydrops; extralobar pulmonary sequestration; fetal pleural effusion; fetoscopic laser photocoagulation; ablation of anastomotic vessels; spina bifida myelomeningocele repair; sacrococcygeal teratoma; twin-to-twin transfusion syndrome; urinary tract obstruction, fetoscopic surgery.

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## Coverage policy

Fetal surgery in utero is clinically proven and therefore, medically necessary, for the following conditions and/or diagnoses:

- Myelomeningocele repair (American College of Obstetricians and Gynecologists, 2017).
- Cord occlusion or ablation for twin reversed arterial syndrome (Mone, 2016).
- Fetoscopic laser photocoagulation, amnioreduction, or radiofrequency ablation for twin-to-twin transfusion syndrome (National Institute for Health and Care Excellence, 2006a, Yoda 2019)).
- Vesico-amniotic shunt or cystoscopy for urinary tract infection or obstruction (National Institute for Health and Care Excellence, 2006b, 2007).
- Open surgery, radiofrequency ablation, interstitial laser ablation, or ultrasound-guided aspiration for tumors or cysts (National Institute for Health and Care Excellence, 2006c).

Limitations

Fetal surgery in utero is investigational and, therefore, not medically necessary for any of the following conditions:

- Fetal tracheal occlusion for congenital diaphragmatic hernia.

- Amnioexchange procedure for gastroschisis.
- Treatment of cleft lip and/or palate.
- Treatment for aquaductal stenosis (i.e., hydrocephalus).
- Amniotic band syndrome.
- Treatment of congenital heart defects.
- In utero gene therapy.
- In utero hematopoietic stem cell transplantation for stem cell diseases.

All other uses of fetal surgery in utero are not medically necessary.

Alternative covered services

Post-delivery and obstetrical management and treatment.

## Background

For decades, experimental fetal surgery proved essential in studying normal fetal physiology and development, and pathophysiology of congenital defects. Clinical fetal surgery started in the 1960s with intrauterine transfusions. In the 1970s, the advent of ultrasonography revolutionized fetal diagnosis and created a therapeutic vacuum. Fetal treatment, medical and surgical, is slowly trying to fill the gap. Most detected defects are best treated after birth and require a modification in the time, mode, and place of delivery for optimal obstetrical and neonatal care (Koehler, 2020).

Fetal intervention can be considered when preterm delivery is contraindicated and the condition can be corrected allowing for normal development. Experts generally recommend early surgical intervention after a confirmed diagnosis of fetal decompensation. In the latter part of pregnancy, standard treatment consists of early delivery and medically necessary interventions rather than fetal surgery.

While 80% of anomalies develop before the 12$^{th}$ week of gestation (Maselli, 2016), the sensitivity of a two-dimensional ultrasound at 11-14 weeks gestation to detect anomalies is 50%, a number that rises to 92.4% at 22-24 weeks gestation (Souka, 2006). Magnetic resonance imaging can sometimes be used in place of ultrasound for diagnostic purposes.

Conditions that are considered for fetal surgery include:

Myelomeningocele.
A neural tube defect; the most severe form of spina bifida, is the most commonly observed malformation of the central nervous system, affecting more than 1,000 fetuses annually in the United States (American College of Obstetricians and Gynecologists, 2017) .

Twin-to-twin transfusion syndrome.
This condition is a complication unique to monochorionic identical twin pregnancies, in which twins share a common placenta, and unequal blood exchange from one twin (donor) to the co-twin (recipient) occurs through placental arteriovenous anastomoses resulting in the two growing at different rates and experiencing different complications from it. Seventy percent of identical twins share a placenta and this occurs in 15-20% of them (Yoda, 2019).

Urinary tract infection or obstruction.
In the fetus, obstruction to the flow of urine out of the bladder causes backup of urine and damage to the kidneys. The most common cause of bladder obstruction is posterior urethral valves in males, although the condition may be linked to a genetic abnormality (National Institute for Health and Care Excellence, 2017).

Tumors.
Fetal tumors observed are rare. One of the most common of these is a sacrococcygeal teratoma, a tumor derived from more than one embryonic germ layer. Most tumors are benign, but the odds of malignancy increase with age (Fetal Care Center of Cincinnati, 2018).

## Findings

Several professional society guidelines have been developed in response to the necessity for correction of various fetal conditions for which surgery is recommended. Most have been provided by the National Institute for Health and Care Excellence in 2006 and 2007; one by the American College of Obstetricians and Gynecologists (2017), and the Congress of Neurological Surgeons (2019) published six separate peer-reviewed journal articles governing the treatment of fetal myelomeningocele, including surgical approaches .

In 2011, Vanderbilt University researchers prepared a report for the Agency for Healthcare Research and Quality on seven types of fetal surgeries, including interventional literature summaries for each type (Walsh, 2011):

- Severe fetal cardiac anomaly surgery.
- Congenital diaphragmatic hernia.
- Myelomeningocele/spina-bifida.
- Obstructive uropathy.
- Sacrococcygeal teratoma.
- Thoracic lesions.
- Twin-twin transfusion syndrome.

Myelomeningocele/spina bifida:

- A trial of 158 fetuses found shunt replacement rates were 40% and 82% for subjects with prenatal and postnatal surgery. At 30 months, the prenatal surgery group had a higher composite score for mental development and motor function ($P = .007$), along with hindbrain herniation by 12 months and ambulation by 30 months. The prenatal group had higher rates of preterm delivery and uterine dehiscence at delivery (Adzick, 2011).
- A review of 19 studies showed that 12 months after treatment, open and endoscopic approaches to fetal surgery for Spina bifida had similar ventriculo-peritoneal shunt placement (40% versus 45%) (Araujo, 2016).
- A review of six studies comparing prenatal and postnatal surgical repair for spina bifida found a similar risk of neurodevelopmental impairment at age 12 months (Inversetti, 2019).
- A review of 11 studies comparing fetoscopic and open/laparotomy repair of myelomeningocele documented similar mortality and shunt placement (for hydrocephalus) rates. Fetoscopic repair had elevated rates of premature rupture of membranes ($P < .01$) and preterm births ($P = .04$) compared to open repair, but had lower rates of preterm births compared to laparatomy. Fetoscopic repair had higher rates of dehiscence and leakage from the repair site ($P < .01$). Authors conclude that fetoscopic repair is a promising alternative to surgery for myelomeningocele, pending improvement in dehiscence and leakage (Kabagambe, 2018).

- A review of five studies comparing fetoscopic and open repair for spina bifida aperta revealed similar perinatal mortality, uterine thinning, dehiscence, and shunt rates at 12 months. In addition, fetoscopic cases resulted in higher rates of prematurity, and more additional postnatal procedures (Joyeux, 2016).
- A review of 11 studies of prenatal surgery for myelomeningocele revealed a 78.6% overall rate of maternal and obstetric complications, mostly obstetric. The most common is spontaneous or preterm membrane rupture (42.0%) (Licci, 2019).
- A review of 298 fetoscopic surgical patients compared to 648 postnatal surgery patients were found to have lower frequencies of hydrocephalus induced cerebral spinal fluid diversion and Chiari decompression than what was received by the postnatal patients (Worley, 2021).

Twin reversed arterial perfusion:

- A review of 26 studies comparing surgery (cord occlusion or ablation) with conservative management for twin reversed arterial perfusion sequence showed superior survival for surgical cases (*P* = .008). Survival was better for ablation than for cord occlusion (*P* = .01) (Mone, 2016).
- A study of 98 fetuses with twin reversed arterial perfusion percutaneous who underwent radiofrequency ablation found that the mean gestational age at delivery was 37.0 weeks and survival of the pump twin to 30 days was 80%, with no maternal deaths (Lee, 2013).
- A review of 10 studies of twin reversed arterial perfusion compared those treated with intrafetal laser therapy. The neonatal survival rate was 80%, and adverse outcomes from pregnancy was significantly reduced when treatment was performed prior to 16 weeks' gestation (*P* = .0025) (Pagani, 2013).

Twin-to-twin transfusion syndrome:

- A systematic review/meta-analysis of 13 studies found intrauterine death rates for twin-to-twin transfusion syndrome were 19.0%, 32.4%, and 12.5% in twins managed expectantly, those who received laser treatment, and 12.5% in those treated with amnioreduction. Neonatal death rates were 22.6%, 24.7%, and 20.2% (D'Antoni, 2020).
- A systematic review/meta-analysis of 15 studies (n = 888) of twin-to-twin transfusion syndrome found In cases not undergoing intervention, miscarriage occurred in 11.0% of fetuses. Incidence of intrauterine deaths, neonatal deaths, and perinatal deaths were 25.2%, 12.2% and 31.2%. In cases treated by laser surgery, the incidence of miscarriage was 19.6%, and 19.6%, 27.4%, 7.4% and 35.9% for intrauterine deaths, neonatal deaths, and perinatal deaths (Murgano, 2020).
- A review of 18 studies (n = 433) found three measures of survival (overall, double, and at least one) rates were similar, whether managed expectantly or treated with amnioreduction. Laser surgery had the highest survival rate (81%, compared with 68% for those managed expectantly and 54% for those undergoing amnioreduction (Khalil, 2016).
- A review of 34 studies (n = 3,868) monochorionic twin pregnancies documented an increase in average survival of both twins increased (35% to 65%, *P* = .012) and at least one twin (70% to 88% (*P* = .009) in the past 25 years, attributing the change to the introduction of laser therapy for twin-to-twin transfusion syndrome (Akkermans, 2015).
- A review of 17 studies comparing monochorionic pregnancies with radiofrequency ablation (n = 320) or bipolar cord occlusion (n = 480) determined the co-twin death rate was insignificantly higher for radiofrequency ablation (14.7% versus 10.6%, *P* = .11) (Gaerty, 2015).
- A review of five studies on fetuses with twin transfusion syndrome produced a significant seven-fold higher risk of severe cerebral injury in live births treated with amnioreduction versus laser surgery (van Klink, 2013).

- A review of 1,376 cases showed iatrogenic pre-term pre-labor rupture of membranes for placental laser in twin-to-twin transfusion syndrome was 27%, similar to shunting in lower urinary tract obstruction (31%) and interventions for twin-reversed arterial perfusion (26%) (Beck, 2012).

A review of 15 studies (n = 895) revealed neurologic morbidity in cases treated with laser therapy for twin-to-twin transfusion syndrome to be 6.1% at birth, and 11.1% at follow-up 28 days after birth, the most common type of morbidity being cerebral palsy (Rossi, 2011).Urinary tract infection:

- A systematic review/meta-analysis of 10 studies (n = 355) of fetuses with lower urinary tract obstruction found survival of vesico-amniotic shunt performed in the second trimester was higher than those cases treated conservatively (57.1% versus 38.8%) (Saccone, 2020).
- A review of 10 studies (n = 355) of fetuses with severe congenital urinary tract obstruction included nine analyzing the effects of vesico-amniotic shunt performed in the second trimester, compared to the group conservatively treated. The shunt group had significantly higher survival (57.1% versus 38.8%) and post-natal (6 - 24 months) renal function (Saccone, 2018).
- A review of nine studies (n = 246) of fetal lower urinary tract obstruction compared those treated with vesico-amniotic shunt and conservatively. The shunt group had superior perinatal survival, but no differences were observed in 6 - 12 month survival, two-year survival, or postnatal renal function (Nassr, 2017a).
- A review of four studies (n = 63) fetuses treated with lower urinary tract obstruction revealed that vesico-amniotic shunt produced no significant differences with those treated with fetal cystoscopy in perinatal survival (Morris, 2011).

Fetal tumors/cysts:

- A review of 92 non-randomized studies (n = 380) analyzed 324 observed and 56 aspirated cysts. Cysts that underwent ultrasound-guided aspiration had a significantly lower rate of postnatal surgery ($P <$ .001) than those treated conservatively. The rate of prenatal torsion in simple cysts ≥ 40 mm was lower in aspirated cysts ($P$ = .03) (Tyraskis, 2017).
- A systematic review/meta-analysis of 34 studies (n = 954) showed that in fetuses undergoing prenatal aspiration of the cyst, recurrence was 37.9%, ovarian torsion and intracystic hemorrhage were diagnosed after birth in 10.8% and 12.8%, and 21.8% had surgery after birth (Bascietto, 2017).
- A review of 59 studies (n = 70) of fetuses with pericardial teratoma contrasted prenatal treatment and non-intervention. Of those treated that were hydropic at intervention, 75.0% had a favorable outcome, compared to 30.8% for controls that developed hydrops (Nassr, 2017b).
- A systematic review/meta-analysis of 10 studies showed the ability of prenatal ultrasound to detect gastrointestinal cysts, which are typically benign, at 94.5% for sensitivity and 97.1% for specificity. Just over half (50.6%) had surgery, and surgical complications occurred in 6.1% of cases (Marrone, 2016).
- A review of 20 fetal sacrococcygeal teratomas revealed survival rates of 30% after minimally invasive surgery, 45% after radiofrequency ablation or interstitial laser ablation, and 55% after open fetal surgery (Van Mieghem, 2014).
- A literature review observed that the optimal treatment for fetal teratomas is complete resection of the mass in utero (Peiro, 2016).

Other conditions:
Surgery has been performed for other conditions affecting the fetus. A relatively common one of these conditions is diaphragmatic hernia, treated with fetoscopic endotracheal occlusion.

- A review of one randomized controlled trial and 17 case studies analyzed results of occlusion for severe congenital diaphragmatic hernia. The procedure increased neonatal survival at 30 days and six months, but was associated with more frequent membrane ruptures, preterm births (< 37 weeks), and a lower (average of two weeks) gestational age at birth. Data were assessed as low quality (Araujo, 2017).
- A systematic review/meta-analysis of 211 fetuses with severe pulmonary hypoplasia and isolated congenital diaphragmatic hernia compared those who did (n = 110) and did not (n = 101) undergo tracheal occlusion. Survival outcome was significantly higher (odds ratio 13.32) in those undergoing the procedure (Al-Maary, 2016).
- A non-randomized study of 210 severe diaphragmatic hernia cases who underwent occlusion showed a high (47.1%) incidence of spontaneous preterm pre-labor rupture of membranes, along with a substantial improvement in survival (Jani, 2009).
- A Cochrane review of 11 studies of fetuses with diaphragmatic hernia included two (n = 65) that addressed tracheal occlusion versus standard management. No survival data was available, and thus no conclusions on efficacy could be drawn (Grivell, 2015).
- A systematic review of nine studies could find no support for fetoscopic endoluminal tracheal occlusion for congenital diaphragmatic hernia (Cundy, 2014).
- A systematic review/meta-analysis of three randomized trials found that fetuses with severe diaphragmatic hernia who underwent endoscopic tracheal occlusion had significantly greater survival than those given standard treatment (27/48 versus 12/52, $P < .0008$) (Shan, 2014).
- A study of 72 fetuses with severe diaphragmatic hernia demonstrated a significantly higher survival rate in the occlusion group than in the no-surgery group (54.3% versus 5.4%, $P < .01$) (Ruano, 2012).
- Similar results were obtained in a controlled trial of 27 subjects (Ruano, 2013).

## References

On November 8, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “fetal surgery,” “myelomeningocele,” “tumors,” “twin reversed arterial syndrome,” “twin-to-twin transfusion syndrome,” and “urinary tract obstruction.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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## Policy updates

1/2013: initial review date and clinical policy effective date: 6/2014

10/2019: Policy references updated.

2/2021: Policy references updated.

2/2022: Policy references updated.