

Policy: MP059

Section: Medical Benefit Policy

Subject: Fetal Surgery

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Fetal Surgery

II. Purpose/Objective:

To provide a policy of coverage regarding Fetal Surgery

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Fetal surgery involves opening the uterus (either by traditional cesarean surgical incision or through single or multiple fetoscopic port incisions), surgically correcting a fetal abnormality, then returning the fetus to the uterus and closing the uterus.

INDICATIONS: REQUIRES PRIOR MEDICAL DIRECTOR OR DESIGNEE AUTHORIZATION

The Plan will cover intrauterine fetal surgery (IUFS) for the following indications:

- Congenital cystic adenomatoid malformations
- Urinary tract obstruction
- Hydronephrosis
- Acardiac twins
- High risk sacrococcygeal teratomas (SCT)
- Twin reversed arterial perfusion
- Myelomeningocele repair
- Fetal cord ligation for twin to twin transfusion*
*only in the event of 100% predicted infant mortality without intervention

The Plan will cover fetoscopic endoluminal tracheal occlusion (FETO) for the intrauterine treatment of congenital diaphragmatic hernia (CDH) when the following criteria are met:

- Diagnosis of CDH is made before 30 weeks of gestation
- Severe pulmonary hypoplasia defined as a quotient of the observed-to-expected lung-to-head ratios of less than 25.0%
- Absence of other known major structural defects

LIMITATIONS:

Requests for in utero fetal surgery for indications not listed in this policy will be reviewed on a per-case basis, utilizing current published peer-reviewed medical literature and assessments by currently contracted technology assessment vendors.

EXCUSIONS:

The Plan does **NOT** provide coverage for in utero stem cell transplantation and in utero gene therapy because it is considered to be **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Fetal surgery

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

- 59072 Fetal umbilical cord occlusion, including ultrasound guidance
- 59074 Fetal fluid drainage (e.g., vesicocentesis, thoracocentesis, paracentesis), including ultrasound guidance
- 59076 Fetal shunt placement, including ultrasound guidance
- S2400 Repair, congenital diaphragmatic hernia in the fetus using temporary tracheal occlusion, procedure performed in utero
- S2401 Repair, urinary tract obstruction in the fetus, procedure performed in utero
- S2402 Repair, congenital cystic adenomatoid malformation in the fetus, procedure performed in utero

S2403 Repair, extralobar pulmonary sequestration in the fetus, performed in utero
S2404 Repair, myelomeningocele in the fetus, procedure performed in utero
S2405 Repair of sacrococcygeal teratoma in the fetus, procedure performed in utero
S2409 Repair, congenital malformation of fetus, procedure performed in utero, not otherwise classified
S2411 Fetoscopic laser therapy for treatment of twin-to-twin transfusion syndrome
S2400 Repair, congenital diaphragmatic hernia in the fetus using temporary tracheal occlusion, procedure performed in utero

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Dommergues M, Louis-Sylvestre C, et.al., "Congenital Adenomatoid Malformation of the Lung: When is Active Fetal Therapy Indicated?", *American Journal of Obstetrics & Gynecology*, 177(4):953-958, Oct 1997.

Adzick NS, Harrison MR, et.al., "Fetal Lung Lesions: Management and Outcome", *American Journal of Obstetrics & Gynecology*, 179(4):884-889, Oct 1998.

Adzick NS, Harrison MR, et. al., "Open Fetal Surgery for Congenital Cystic Adenomatoid Malformation of the Lung", *American Journal of Obstetrics and Gynecology*, 178(1S)Supplement:28S, Jan 1998.

Alexander JM, Ramus R, Cox S, Gilstrap LC, "Outcome of Twin Gestations With a Single Anomalous Fetus", *American Journal of Obstetrics & Gynecology*, 177(4):849-852, Oct 1997.

Crombleholme TM, Robertson F, Marx G, Yarnell R, D'Alton ME, "Fetoscopic Cord Ligation to Prevent Neurological Injury in Monozygous Twins", *Lancet*, 348(9021):191, July 20, 1996.

Gloor JM, "Management of Prenatally Detected Fetal Hydronephrosis", *Mayo Clinic Proceedings*, 70(2):145-152, Feb 1995.

Allen MH, Garabelis NS, Bornick PW, Quintero RA, "Minimally Invasive Treatment of Twin-to-Twin Transfusion Syndrome", *AORN Journal*, 71(4):795-796, 801-812, 815-818, Apr 2000.

Geisinger Technical Assessment Committee, Fetal Surgery, Oct 14, 1998, Jan 13, 1999, April 14, 1999.

Hartmann, Katherine E. MD, PhD; McPheeters, Melissa L. PhD, MPH; et al. "Evidence to Inform Decisions About Maternal-Fetal Surgery: Technical Brief" *Obstetrics & Gynecology* 117(5) 1191-1204 May, 2011

Uptodate. Sacrococcygeal germ cell tumors. Updated Feb. 21, 2014. <http://www.uptodate.com/contents/sacrococcygeal-germ-cell-tumors>

Walsh WF, Chescheir NC, Gillam-Krakauer M et al. Maternal-fetal surgical procedures. Comparative Effectiveness Technical Briefs, No. 5. Rockville (MD): Agency for Healthcare Research and Quality (US) 2011 Apr. Report No. 10(11)-EHC059-EF. Available online at: <http://www.ncbi.nlm.nih.gov/books/NBK54520/pdf/TOC.pdf>.

Araujo Junior E, Tonni G, Chung M, et al. Perinatal outcomes and intrauterine complications following fetal intervention for congenital heart disease: Systematic review and meta-analysis of observational studies. *Ultrasound Obstet Gynecol*. 2016 Jan 22

Holland MG, Mastrobattista JM, Lucas MJ. Diagnosis and management of twin reversed arterial perfusion (TRAP) sequence. UpToDate. Waltham, MA: UpToDate

Moise KJ, Jr., Johnson A. Management of twin-twin transfusion syndrome. UpToDate. Waltham, MA: UpToDate.

Adzick NS, Thom EA, Spong CY, et al. A randomized trial of prenatal versus postnatal repair of myelomeningocele. *N Engl J Med*. 2011;364(11):993-1004.

Committee on Obstetric Practice, Society for Maternal–Fetal Medicine. Committee Opinion No. 720: Maternal-Fetal Surgery for Myelomeningocele. *Obstet Gynecol.* 2017 Sep;130(3):e164-e167.

Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 187: Neural Tube Defects. *Obstet Gynecol.* 2017 Dec;130(6):e279-e290.

Hayes, Inc. Directory. In utero fetal surgery for myelomeningocele. July 23, 2018.

Farmer DL, Thom EA, Brock JW 3rd, et al. The Management of Myelomeningocele Study: full cohort 30-month pediatric outcomes. *Am J Obstet Gynecol.* 2018; 218(2):256.e1-256.e13.

Kabagambe SK, Jensen GW, Chen YJ, et al. Fetal surgery for myelomeningocele: a systematic review and metaanalysis of outcomes in fetoscopic versus open repair. *Fetal Diagn Ther.* 2018;43(3):161-174

Witlox R, S, G, M, Lopriore E, Rijken M, et al: Long-term neurodevelopmental and respiratory outcome after intrauterine therapy for fetal thoracic abnormalities. *Fetal Diagn Ther* 2019;45:162-16

Dugas A, Larghero J, Zerah M, et al. Cell therapy for prenatal repair of myelomeningocele: A systematic review. *Curr Res Transl Med.* 2020;68(4):183-189.

Peranteau WH, Flake AW. The future of in utero gene therapy. *Mol Diagn Ther.* 2020;24(2):135-142.

Hii LY, Sung CA, Shaw SW. Fetal surgery and stem cell therapy for meningomyelocele. *Curr Opin Obstet Gynecol.* 2020;32(2):147-151.

Kunpalin Y, Subramaniam S, Perin S, et al. Preclinical stem cell therapy in fetuses with myelomeningocele: A systematic review and meta-analysis. *Prenat Diagn.* 2021;41(3):283-300

Stirnemann J, Slaghekke F, Khalek N, et al. Intrauterine fetoscopic laser surgery versus expectant management in stage 1 twin-to-twin transfusion syndrome: an international randomized trial. *Am J Obstet Gynecol.* 2021 May;224(5):528.e1-528.e1

Molina-Giraldo S, Salcedo RZ, Arias JLR, et al. Open surgery for in utero repair of spina bifida: Microneurosurgery versus standard technique - A systematic review. *Prenat Diagn.* 2021;41(13):1615-1623

Cole FS. Fetal tracheal occlusion for congenital diaphragmatic hernia. *N Engl J Med.* 2021;385(2):177-178

Deprest JA, Nicolaidis KH, Benachi A, et al.; TOTAL Trial for severe hypoplasia investigators. Randomized trial of fetal surgery for severe left diaphragmatic hernia. *N Engl J Med.* 2021a Jul 8;385(2):107-118.

Deprest JA, Benachi A, Gratacos E, et al.; TOTAL Trial for moderate hypoplasia investigators. Randomized trial of fetal surgery for moderate left diaphragmatic hernia. *N Engl J Med.* 2021b Jul 8;385(2):119-129.

Chang YL, Hsu CC, Chao AS, Chang SD, Cheng PJ, Li WF. Effect of Fetoscopic Laser Photocoagulation on Fetal Growth and Placental Perfusion in Twin-Twin Transfusion Syndrome. *J Clin Med.* 2022 Jul 28;11(15):4404.

Mustafa HJ, Javinani A, Goetzinger K, et al. Single fetal demise following fetoscopic ablation for twin-to-twin transfusion syndrome-cohort study, systematic review, and meta-analysis. *Am J Obstet Gynecol.* 2022 Jun;226(6):843.e1-843.e28.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 10/98

Revised: 4/99, 7/02, 7/03 (add limitation); 8/04, 8/14(added indication); 7/16 (add indications); 8/18 (added indication); 8/21 (add gene therapy exclusion); 8/22 (add Indication FETO for CDH)

Reviewed: 8/05; 8/06; 8/07, 9/08, 9/09, 7/10, 8/11, 8/12, 8/13, 8/15, 7/17. 8/19, 8/20, 8/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.