Clinical Policy: Fetal Surgery in Utero for Prenatally Diagnosed Malformations

Reference Number: WNC.CP.123
Last Review Date: 04/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description

This policy describes the medical necessity requirements for performing fetal surgery. This becomes an option when it is predicted that the fetus will not live long enough to survive delivery or after birth. Therefore, surgical intervention during pregnancy on the fetus is meant to correct problems that would be too advanced to correct after birth.

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that in-utero fetal surgery (IUFS) is medically necessary for the following indications:

A. Sacrococcygeal teratoma (SCT): SCT resection or a minimally invasive approach;
B. Lower urinary tract obstruction without multiple fetal anomalies or chromosomal abnormalities: urinary decompression via vesico-amniotic shunting;
C. Congenital pulmonary airway malformation (CPAM) and extralobar bronchopulmonary sequestration (BPS), with high risk tumors: resection of malformed pulmonary tissue, or placement of a thoraco-amniotic shunt;
D. Placement of a thoraco-amniotic shunt for pleural effusion with or without secondary fetal hydrops;
E. Twin-twin transfusion syndrome (TTTS): treatment approach is dependent on Quintero stage, maternal signs and symptoms, gestational age and the availability of requisite technical expertise **and** include either:
    1. Amnioreduction; **or**
    2. Fetoscopic laser ablation, with or without amnioreduction when member is between 16 and 26 weeks gestation;
F. Twin-reversed-arterial-perfusion sequence (TRAP): ablation of anastomotic vessels of the acardiac twin (laser, radiofrequency ablation);
G. Myelomeningocele: repair when **all** of the following criteria are met:
    1. Singleton pregnancy;
    2. Upper boundary of myelomeningocele located between T1 and S1;
    3. Evidence of hindbrain herniation;
    4. Gestational age 19.0 to < 26 weeks;
    5. Normal fetal karyotype (exceptions may apply at the discretion of the provider after genetic counseling with shared decision-making with the patient); and
    6. **None** of the following:
        a. Severe kyphosis;

b. Risk of preterm birth (e.g., transvaginal cervical length at time of surgery < 20 mm, prior spontaneous preterm birth < 32 weeks, history of cervical insufficiency, cerclage present);
c. Placenta previa at the time of surgery;
d. Placental abruption;
e. Maternal body mass index of ≥ 35;
f. Maternal HIV, Hepatitis B and/or Hepatitis C
g. Multiple maternal medical conditions that independently increase the risk of pre-term birth; e.g., chronic renal disease/renal insufficiency, systemic lupus erythematous (SLE), maternal cardiac disease, preexisting diabetes
h. Previous hysterotomy in the active uterine segment.

II. It is the policy of WellCare of North Carolina that all repeat utero fetal surgery procedures require secondary review.

III. It is the policy of WellCare of North Carolina® that current evidence does not support the use of utero fetal surgery for any of the following indications:

A. Open or endoscopic fetal surgery for congenital diaphragmatic hernia (CDH), including temporary tracheal occlusion;
B. Surgery for heart block, pulmonary valve, or aortic obstruction;
C. Tracheal atresia or stenosis;
D. Cleft lip and palate;
E. In-utero stem cell transplantation;
F. In-utero gene therapy;
G. Amnioexchange procedure for gastroschisis.

Background

Maternal–fetal surgery

Maternal–fetal surgery is a major procedure for the mother and her fetus, and it has significant implications and complications that could occur acutely, postoperatively, for the duration of the pregnancy, and in subsequent pregnancies. For the fetus, safety and effectiveness are variable, and depend on the specific procedure, the reasons for the procedure, and the gestational age and condition of the fetus. Often babies who have been operated on in this manner are born pre-term. Therefore, it should only be offered at facilities with the expertise, multidisciplinary teams, services, and facilities to provide the intensive care required for these patients.

Fetal surgery approaches can be divided into two categories:

- Open fetal surgery is considered when the fetal condition is life threatening, and the intervention is felt to be the only option for fetal survival. A hysterotomy is performed, the fetus is partially removed to expose the area that needs surgery, the fetal abnormality is corrected, and the fetus is returned to the uterus where it continues to develop until delivery.
- Fetoscopic surgery employs minimally invasive techniques and uses small fiberoptic telescopes and instruments to enter the uterus through small surgical openings to correct congenital malformations without major incisions or removing the fetus from the womb. This interim procedure is less traumatic, reduces the chances of preterm labor, and allows the fetus to remain in utero until it has matured enough to survive delivery and neonatal surgical procedures.

Sacrococcygeal germ cell tumors

The prenatal diagnosis of SCT typically occurs during the second trimester during routine sonography. Prenatal diagnosis and close monitoring have improved outcomes for fetal SCT, but overall perinatal mortality remains high. The major goal is to identify fetuses at increased risk of fetal demise because of hydrops fetalis and intervene as appropriate, Hydrops fetalis is a condition of excess fluid accumulation in the fetus that results in significant fetal demise and neonatal mortality. Although criteria for open fetal surgery vary across centers, most include fetuses with high-risk SCT and hydrops developing at a gestational age earlier than appropriate for delivery and neonatal care (eg, 28 to 32 weeks gestation). Contraindications to open fetal surgery for SCT include type III or IV Altman type tumors, severe placentomegaly, cervical shortening, and maternal medical issues. [9]

Lower Urinary Tract Obstruction

The prenatal diagnosis of lower urinary tract obstructions typically occurs during the first or second trimester during routine sonography. Outcomes range from clinically insignificant to inutero fetal demise. Vesicoamniotic shunts can be a temporizing measure and provide a survival advantage in a select cohort of fetuses with urinary tract obstruction. [19]

Congenital pulmonary airway malformation

CPAM is one of the most common lung lesions diagnosed prenatally, although the birth prevalence is quite low. Prenatal diagnosis is typically made by ultrasonography. CPAMs presenting prenatally are classified macrocystic or microcystic based on ultrasound appearance. Approximately, 50% of the masses resolve before delivery while the remainder persists until delivery. Hydrops can develop with either micro or macrocystic lesions due to hemodynamic alterations from vena cava obstruction, cardiac displacement/compression and require prenatal intervention. The presence of hydrops is a sign for impending fetal demise (risk of death approaches 100 percent in the absence of intervention) and thus it is an indication for fetal intervention. For hydropic fetuses over 32 to 34 weeks of gestation, early delivery with immediate postnatal resection is a reasonable option. Ex utero intrapartum therapy (EXIT) has been used to stabilize fetuses with large lesions expected to have difficulty breathing at delivery. In EXIT, the fetus is partially delivered and intubated without clamping the umbilical cord. Uteroplacental blood flow and gas exchange are maintained by using inhalational agents to provide uterine relaxation and amnioinfusion to maintain uterine volume. This provides time for resection of the lung mass prior to complete delivery of the infant. For hydropic fetuses between 20 and 32 weeks of gestation, the choice of the best invasive approach depends on the type of anomaly (macro- versus microcystic). Drainage procedures are used for CPAMS with dominant cysts, while solid masses are treated by resection or ablation. [10]

Twin-twin transfusion syndrome

TTTS occurs in approximately 10–15% of monochorionic–diamniotic twin pregnancies and results from the presence of arteriovenous anastomoses in a monochorionic placenta. In the affected pregnancy, there is an imbalance in the fetal–placental circulations, whereby one twin transfuses the other. It usually presents in the second trimester. Once the diagnosis of twin–twin transfusion syndrome has been made, the prognosis depends on gestational age and severity of the syndrome. Staging is commonly performed via the Quintero staging system and treatment is by laser coagulation or amnioreduction, often in collaboration with an expert in twin–twin transfusion syndrome diagnosis and management.[18]

Twin reversed-arterial-perfusion

Twin reversed-arterial-perfusion sequence (TRAP) is a rare unique serious complication of monochorionic twin pregnancy in which a twin with an absent or a nonfunctioning heart,

("acardiac twin"), is perfused by its co-twin ("pump twin") via placental arterial anastomoses. The acardiac twin usually has a poorly developed heart, upper body, and head. The pump twin is at risk of heart failure and problems related to preterm birth. Current treatment modalities target occlusion of the umbilical cord of the acardiac twin and include laser coagulation, bipolar cord coagulation, and radiofrequency ablation (RFA).[12]

Guideline Recommendations

The American College of Obstetricians and Gynecologists and the Society for Maternal–Fetal Medicine have developed recommendations for myelomeningocele repair. Open maternal–fetal surgery for myelomeningocele repair has been demonstrated to improve a number of important pediatric outcomes at the expense of procedure-associated maternal and fetal risks. Women with pregnancies complicated by fetal myelomeningocele who meet established criteria for in utero repair should be counseled in nondirective fashion regarding all management options, including the possibility of open maternal–fetal surgery. Interested candidates for fetal myelomeningocele repair should be referred for further assessment and consultation to a fetal therapy center that offers this intervention and possesses the expertise, multi-disciplinary team, services, and facilities to provide detailed information regarding maternal–fetal surgery and the intensive care required for patients who choose to undergo open maternal–fetal surgery.[8]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
59001	Amniocentesis; therapeutic amniotic fluid reduction (includes ultrasound guidance)
59076	Fetal shunt placement, including ultrasound guidance
59897	Unlisted fetal invasive procedure, including ultrasound guidance, when performed

HCPCS ®* Codes	Description
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, procedure 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

HCPCS ®* Codes	Description
S2409	Repair congenital malformation of fetus, procedure performed in utero, not otherwise classified
S2411	Fetoscopic laser therapy for treatment of twin-to-twin transfusion

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
D43.4	Neoplasm of uncertain behavior of spinal cord
O30.021- O30.029	Conjoined twin pregnancy [twin reversed arterial perfusion (TRAP)]
O31.031-O31.039	Twin pregnancy, monochorionic/diamniotic
O35.0XX0-O35.9XX9	Maternal care for known or suspected fetal abnormality and damage
O36.20X0-O36.23X9	Maternal care for hydrops fetalis
O43.021 - O43.029	Fetus-to-fetus placental transfusion syndrome
Q05.0-Q05.9	Spina Bifida
Q33.0	Congenital cystic lung
Q33.2	Sequestration of lung
Q33.3	Agenesis of lung
Q33.6	Congenital hypoplasia and dysplasia of lung
Q34.0-Q34.9	Other congenital malformations of respiratory system
Q62.31-Q62.39	Other obstructive defects of renal pelvis and ureter
Q64.2	Congenital posterior urethral valves
Q64.31-Q64.39	Other atresia and stenosis of urethra and bladder neck
Q89.4	Conjoined twins
Q89.8	Other specified congenital malformations

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	02/21	05/21
Added Sections I.D. and II. Revised Section I.G.6.e. (BMI). Updated investigational verbiage in Section III. References reviewed and updated.	04/22	

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North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
   2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in this policy.
b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   EPSDT provider page: https://medicaid.ncdhhs.gov/

EPSDT does not apply to NCHC beneficiaries.

Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and

b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the, NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   Unlisted Procedure or Service
   CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
   HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service
d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
   For NCHC refer to NCHC State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers,

members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.