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1.0 Description of the Procedure, Product, or Service

Heart (cardiac) transplantation is the surgical excision of a heart and the main arteries from a human, brain-dead donor, with subsequent implantation into a beneficiary who has had his heart surgically removed in a similar manner. The new heart is surgically attached to the major blood vessels which include the pulmonary arteries, pulmonary veins, aorta, and the vena cava.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- 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 **Section 3.0 of 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

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.
- b. **NCHC**
None Apply.

2.2 Special Provisions

2.2.1 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.

b. 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: <http://www.ncdhhs.gov/dma/epsdt/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

- a. Medicaid and NCHC shall cover **pediatric** heart (cardiac) transplantation when the beneficiary meets the following criteria:
 1. heart failure with persistent symptoms at rest, requiring one or more of the following:
 - A. continuous infusion of intravenous inotropic agents;
 - B. mechanical ventilator support; or
 - C. mechanical circulatory support.
 2. pediatric heart disease with symptoms of heart failure not meeting the above criteria but having:
 - A. severe limitation of exercise and activity (if measurable, beneficiary would have a peak maximum oxygen consumption less than 50% predicted for age and sex);
 - B. cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease;

- C. near sudden death or life-threatening arrhythmias untreatable with medications or an implantable defibrillator;
 - D. restrictive cardiomyopathy with reactive pulmonary hypertension;
 - E. reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future;
 - F. anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; or
 - G. anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.
- b. Medicaid and NCHC shall cover heart (cardiac) transplantation for **adult** Medicaid or NCHC beneficiaries with end-stage, irreversible, refractory, symptomatic heart disease requiring maximal continuous medical or mechanical support and who have:
- 1. a low functional status;
 - 2. a poor probability of survival; and
 - 3. one of the following underlying conditions:
 - A. presence of an implanted ventricular assist device;
 - B. refractory cardiogenic shock;
 - C. dependency on intravenous inotropic support to maintain adequate organ perfusion;
 - D. maximal peak venous oxygenation (V02) of 11-14 milliliters/kilogram/minute (or 55% of predicted) and major limitation of activities;
 - E. severe ischemia (or recurrent unstable ischemia) consistently limiting routine activity not amenable to bypass surgery or percutaneous coronary intervention;
 - F. recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities; or
 - G. ischemic cardiomyopathy not amenable to medical therapy or revascularization procedures.

Retransplantation in a beneficiary with graft failure, due to either technical reasons or hyperacute rejection is considered medically necessary.

Retransplantation in a beneficiary with chronic rejection, moderate graft vasculopathy or recurrent disease is considered medically necessary when the beneficiary meets the general section criteria as outlined above.

The beneficiary and caregiver are willing and capable of complying with the post transplant treatment plan.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

Coverage is not provided for organs sold rather than donated to the beneficiary.

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover heart (cardiac) transplantation when:

- a. Any of the following clinical conditions are present:
 1. Alcoholic cardiomyopathy (unless abstinent for at least six months);
 2. Systemic illness that would limit life expectancy or compromise recovery from cardiac transplantation;
 3. Diabetes mellitus with evidence of significant end-organ complications, such as retinopathy, neuropathy, nephropathy, and peripheral or cerebrovascular disease;
 4. Acute severe hemodynamic compromise at the time of transplant, when accompanied by failure of any vital end-organ, because survival is likely to be compromised;
 5. Severe peripheral vascular disease or cerebrovascular disease;
 6. Current, potentially life-threatening, malignancy;
 7. Active infection (except for infection of a ventricular assist device);
 8. Irreversible hepatic (liver) dysfunction (transaminases twice normal, with associated coagulopathy), irreversible renal (kidney) dysfunction (serum creatinine greater than 2 mg/dl or creatinine clearance less than 50 cc/min);
 9. Chronic bronchitis or chronic obstructive pulmonary disease forced expiratory volume in one second (FEV 1) less than 60% predicted or any irreversible lung disease;
 10. Cachexia, even without major end-organ failure, as survival is significantly less favorable;
 11. Human Immunodeficiency Virus (HIV) positivity;
 12. Morbid obesity indicated by either a body mass index (BMI) greater than 40, or a BMI greater than 35 with comorbid conditions;

13. Absence of documentation of nonsmoking status;
 14. Recent substance use that will likely impair compliance with post transplant protocols;
 15. Beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-transplant medical care, or
 16. Current beneficiary/caretaker non-compliance would make compliance with a disciplined medical regimen improbable.
- b. Pulmonary infarction or embolism during the preceding eight weeks is considered a relative contra-indication; or
 - c. Heart transplants requiring planned concurrent coronary artery bypass graft surgery, as this is considered experimental.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall require prior approval for heart (cardiac) transplantation. The provider shall obtain prior approval before rendering heart (cardiac) transplantation.

Only those beneficiaries accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior review. Guidelines must be followed for transplant network or consortiums, if available.

All applicable Medicaid and NCHC policies and procedures must be followed in addition to the ones listed in this procedure.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy; and
- c. if the Medicaid beneficiary is under 21 years of age, information supporting that all EPSDT criteria are met and evidence-based literature supporting the request, if available.

5.3 Specific Transplant Prior Approval Requirements

The provider(s) shall submit the following to the DMA transplant nurse consultant:

- a. Letter of medical necessity **signed by the attending transplant physician**, requesting transplant, summarizing the clinical history, social history and the transplant evaluation;
- b. All health care records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy including:
 1. Lab results (less than three months old) to include Complete Blood Count (CBC), complete electrolytes, liver enzymes, Prothrombin Time (PT), International Normalized Ratio (INR), glucose and A1C (Glycated Hemoglobin if Type I or Type II diabetic), and blood type;
 2. Baseline drug, alcohol, and nicotine/cotinine screenings on all adult transplant candidates;
 3. Serologies to include Human Immunodeficiency Virus (HIV), Hepatitis, Rapid Plasma Reagin (RPR), Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Varicella, Rubella, Herpes Simplex Virus (HSV) I/II, and toxoplasmosis. (*Positive* serology results may be reported that are greater than three months old);
 4. Diagnostic studies (less than six months old) required in a complete packet include:
 - A. Cardiac: Echocardiogram, Electrocardiogram (ECG), and/or cardiac catheterization as appropriate for beneficiary's clinical status;
 - B. Pulmonary: Pulmonary Function Test if beneficiary has cardiac or pulmonary issues, or a history of smoking; and
 - C. Chest x-ray for all transplant candidates;
 5. Other diagnostic tests may be requested as appropriate;
 6. Beneficiary's height and weight
 7. Results of all diagnostic and procedure results (not more than six months old)
- c. Complete psychological and social evaluation to include:
 1. beneficiary's medical compliance;
 2. beneficiary's support network;
 3. post-transplant care plan, with identification of primary and secondary care providers; and
 4. history of mental health issues/substance use/legal issues

- d. Beneficiaries with a psychiatric history are required to have an evaluation by a psychiatrist with expertise in evaluating the specific psychiatric issues that relate to transplant candidates.

Beneficiaries with a history of alcohol (ETOH)/substance use shall fulfill the following criteria:

- a. Actively using ETOH/substance within the past year
 1. These beneficiaries shall have six months of counseling (at least twice per month)-provided by a substance abuse provider.
 2. Shall have monthly toxicology/ETOH screens, continuing these screens monthly until listed; and
 3. Shall have toxicology/ETOH screens as needed (PRN).
- b. Clean/sober up to 2 years
 1. These beneficiaries shall have a counseling consult and the counselor will decide if the beneficiary requires continued recidivism counseling. Medicaid will accept the counselor's recommendations;
 2. These beneficiaries shall have ONE toxicology/ETOH screen during their evaluation; and
 3. Shall have toxicology/ETOH screens PRN.
- c. Clean/sober for greater than 2 years
 1. No counseling is necessary;
 2. Beneficiary shall have one toxicology/ETOH screen during evaluation; and
 3. Beneficiary shall have toxicology/ETOH screens PRN

6.0 Providers 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 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 DMA'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).
- c. FDA approved procedures, products, and devices for implantation must be utilized for heart (cardiac) transplantation.
- d. A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the beneficiary's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1985

Revision Information:

Date	Section Revised	Change
07/01/2005	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
05/01/2007	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
05/01/2007	Attachment A	Added the UB-04 as an accepted claims form.
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
12/01/11	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.
03/12/2012	Subsection 3.3	Prior approval requirements relocated to Subsection 5.1 Prior Approval
03/12/2012	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11B-2 under Session Law 2011-145, § 10.41.(b)
03/12/2012	Attachment A	Removed the UB-04 claim form from A.
03/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
08/01/2012	Subsection 5.3	Prior authorization requirements for recipients with ETOH/substance abuse issues was added.
08/01/2012	Throughout	Replaced "recipient" with "beneficiary."
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.

Attachment A: Claims-Related Information

Providers shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

B. International Classification of Diseases, 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.

ICD-10 Code(s)
02YA0Z1
02YA0Z0

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.

CPT Code(s)
33940
33945

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

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s)..

F. Place of Service

Acute inpatient hospital

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at

<http://www.ncdhhs.gov/dma/plan/sp.pdf>.

For NCHC refer to G.S. 108A-70.21(d), located at

http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html.

H. Reimbursement

Providers shall bill their usual and customary charges.

For a schedule of rates, see: <http://www.ncdhhs.gov/dma/fee/>

I. Billing for Donor Expenses

Donor transplant-related medical expenses for donors are billed on the Medicaid or NCHC beneficiary's transplant claim using the beneficiary's Medicaid or NCHC identification number.

Medicaid or NCHC reimburses only for the actual donor's transplant-related medical expenses. Medicaid or NCHC does not reimburse for unsuccessful donor searches.

Cadaveric/Deceased Organ Donations:

Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a heart transplant if the transplant beneficiary has received prior approval for a cadaveric/deceased organ transplant procedure.