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## **1.0 Description of the Procedure, Product, or Service**

Beneficiaries with chronic pancreatitis may experience intractable pain that can only be relieved with a total or near total pancreatectomy. The pain relief must be balanced against the certainty that the Medicaid beneficiary will become an insulin dependent diabetic if a pancreatectomy is performed. Autologous islet cell transplantation has been investigated as a technique to prevent this from occurring. During the pancreatectomy procedure, a suspension of isolated islet cells is created from the resected pancreas specimen and then injected into the portal vein of the liver. The cells function as a free graft continuing to make insulin. While the procedure does not prevent insulin dependent diabetes in every case, use of the most recent techniques in islet cell isolation demonstrate about a 55% success rate.

Allogeneic islet transplantation has been researched for use in type 1 diabetes to restore normal glycemia which could reduce long-term complications (i.e., retinopathy, neuropathy, nephropathy, and cardiovascular disease). This procedure is an alternative to pancreas transplantation. It typically requires two or more donor organs to obtain enough cells for islet transplantation. These cells are usually obtained from a pancreas that has been rejected as a whole organ for transplant. Islet transplantation is only recommended for those with frequent and severe metabolic complications who have failed to achieve control with insulin.

Islet cells are regulated by the U.S. Food and Drug Administration (FDA). Allogeneic islet cells are classified as somatic cell therapy which requires premarket approval. Islet cells also fall under the definition of a drug which requires that clinical studies be done to determine the safety and effectiveness of islet transplantation to comply with the investigational new drug (IND) regulation.

### **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 a Medicaid Beneficiary 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**

Medicaid and NCHC shall cover autologous islet transplants when medically necessary and performed together with a total or near total pancreatectomy in Medicaid or NCHC beneficiaries with chronic pancreatitis.

#### **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 a Medicaid Beneficiary 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**

#### **4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC**

Medicaid and NCHC shall not cover islet cell transplantation for any of the following:

- a. allogeneic islet transplantation, as it is considered investigational for the treatment of type I diabetes;
- b. islet cell transplantation for all other indications as it is considered investigational; or
- c. islet cell transplantation when the beneficiary does not meet the criteria in **Subsection 3.2**.

#### **4.2.2 Psychosocial History**

Medicaid and NCHC shall not cover islet cell transplantation when the beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-transplant medical care.

#### **4.2.3 Medical Compliance**

Medicaid and NCHC shall not cover islet cell transplantation when there is a current beneficiary or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

#### **4.2.4 Substance Use**

Medicaid and NCHC shall not cover islet cell transplantation when the beneficiary has an active substance use or, for beneficiaries with a recent history of substance use, there is no documentation of the completion of a substance abuse or therapy program plus six months of negative sequential random drug screens.

#### **4.2.5 Medicaid Additional Criteria Not Covered**

None Apply.

#### **4.2.6 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 a Medicaid Beneficiary under 21 Years of Age.*

#### **5.1 Prior Approval**

Medicaid and NCHC shall require prior approval for islet cell transplantation. The provider shall obtain prior approval before rendering islet cell transplantation.

The provider shall obtain prior approval before rendering islet cell transplantation for a Medicaid and NCHC beneficiary.

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

Only those Medicaid and NCHC 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.

#### **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.

### 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 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.

### **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 a Medicaid Beneficiary 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).

FDA approved procedures, products, and devices for implantation must be utilized for islet cell transplantation.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

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, 1994

### 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. |
| 12/01/2011 | Throughout                   | Policy was updated to include coverage criteria and requirements to meet current community standards of practice.                                                                                                                |
| 12/01/2011 | Subsection 2.1               | Spelled out NC Health Choice                                                                                                                                                                                                     |
| 12/01/2011 | Subsection 3.2               | Updated criteria                                                                                                                                                                                                                 |
| 12/01/2011 | Subsection 4.2               | Updated criteria                                                                                                                                                                                                                 |
| 12/01/2011 | Subsection 4.4               | Added Medical Compliance                                                                                                                                                                                                         |
| 12/01/2011 | Subsection 4.5               | Added Substance Abuse                                                                                                                                                                                                            |
| 12/01/2011 | Subsection 5.2               | Added Prior Approval requirements                                                                                                                                                                                                |
| 12/01/2011 | Section 7.0                  | Updated compliance                                                                                                                                                                                                               |
| 12/01/2011 | Attachment A                 | Updated codes and changed "must" to "shall"                                                                                                                                                                                      |
| 03/12/2012 | Throughout                   | To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11B-3 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

Provider(s) 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.

### 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) |
|-------------|
| 48160       |

| HCPCS Code(s) |
|---------------|
| G0341         |
| G0342         |
| G0343         |

#### 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](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.

Living Organ Donations:

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for the autologous donations are covered for an islet cell transplant if the beneficiary has received prior approval for the procedure.