To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

1.0 Description of the Procedure, Product, or Service 1
1.1 Definitions 1

2.0 Eligibility Requirements 1
2.1 Provisions 1
2.1.1 General 1
2.1.2 Specific 2
2.2 Special Provisions 2
2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age 2

3.0 When the Procedure, Product, or Service Is Covered 3
3.1 General Criteria Covered 3
3.2 Specific Criteria Covered 3
3.2.1 Specific criteria covered by Medicaid 3
3.2.2 Medicaid Additional Criteria Covered 3

4.0 When the Procedure, Product, or Service Is Not Covered 3
4.1 General Criteria Not Covered 3
4.2 Specific Criteria Not Covered 4
4.2.1 Specific Criteria Not Covered by Medicaid 4
4.2.2 Psychosocial History 4
4.2.3 Medical Compliance 4
4.2.4 Medicaid Additional Criteria Not Covered 4

5.0 Requirements for and Limitations on Coverage 4
5.1 Prior Approval 4
5.2 Prior Approval Requirements 4
5.2.1 General 4
5.2.2 Specific 4

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service 4
6.1 Provider Qualifications and Occupational Licensing Entity Regulations 5
6.2 Provider Certifications 5

7.0 Additional Requirements 5
7.1 Compliance 5

8.0 Policy Implementation/Revision Information 6

Attachment A: Claims-Related Information 8
A. Claim Type 8

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) 8
C. Code(s) 8
D. Modifiers 8
E. Billing Units 8
F. Place of Service 8
G. Co-payments 9
H. Reimbursement 9

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 policies*)

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).
b. Provider(s) shall verify each Medicaid 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.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. Medicaid

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: https://medicaid.ncdhhs.gov/

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 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 Medicaid

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

3.2.2 Medicaid 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 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 Medicaid

Medicaid 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 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 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 Medicaid Additional Criteria Not Covered

None Apply.

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 shall not require prior approval for islet cell transplantation.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

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 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 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).

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.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."

Date	Section Revised	Change
03/15/2019	All Sections and Attachments	Updated policy template language.
07/01/2021	Section 4.2.4	Substance use requirements removed.
07/01/2021	Section 5.0	Prior approval requirement removed.
07/01/2021	Attachment A	Added claim type Institutional (UB-04/83711). Removed specific CPT and HCPCS codes. Removed Section I.
8/15/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid. Policy posted 8/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, NCTracks 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.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/83711)

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

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:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/