

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.

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**NC Medicaid
Small Bowel, Small Bowel/Liver
or Multivisceral Transplants**

**Medicaid
Clinical Coverage Policy No: 11B-8
Amended Date: August 15, 2023**

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1.0 Description of the Procedure, Product, or Service

This policy addresses three different transplantation services: 1) small bowel transplant, 2) small bowel/liver transplant, and 3) small bowel/liver and multivisceral transplants.

A small bowel transplant is typically performed in beneficiaries with short bowel syndrome. This is a condition in which the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal of a large portion of small intestine. In adults, etiologies of short bowel syndrome include ischemia, trauma, volvulus, and tumors. In children, gastroschisis, volvulus, necrotizing enterocolitis, and congenital atresia are predominant causes.

The small intestine, particularly the ileum, does have the capacity to adapt to some functions of the diseased or removed portion over a period of one to two years. Prognosis for recovery depends on the degree and location of small intestine damage. Therapy is focused on achieving adequate macro- and micro-nutrient uptake in the remaining small bowel. Pharmacological agents have been studied to increase villous proliferation and slow transit times, and surgical techniques have been advocated to optimize remaining small bowel. Some beneficiaries with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become dependent on total parenteral nutrition (TPN). Beneficiaries with complications from TPN may be considered candidates for small bowel transplant. Complications include catheter-related mechanical problems, infections, hepatobiliary disease, and metabolic bone disease. While cadaveric intestinal transplant is the most commonly performed transplant, there has been recent interest in using living donors.

In some instances, short bowel syndrome is associated with liver failure, often due to the long-term complications of TPN. These beneficiaries may be candidates for a small bowel/liver transplant or a multivisceral transplant, which includes the small bowel and liver with one or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, or colon. A multivisceral transplant is indicated when anatomic or other medical problems preclude a small bowel/liver transplant.

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*); or
- 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 Medicaid Beneficiaries 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 covers small bowel transplant using a cadaveric intestine when medically necessary in adult or pediatric beneficiaries with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance), who have established long-term dependency on TPN and are developing or have developed severe complications due to TPN.

Medicaid covers small bowel transplant using a living donor when medically necessary only when a cadaveric intestine is not available for transplantation in a beneficiary who meets the criteria for a cadaveric intestinal transplant.

Medicaid covers small bowel/liver transplant or multivisceral transplant when medically necessary in pediatric or adult beneficiaries with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance), who have been managed with total parenteral nutrition (TPN) and have developed evidence of impending end-stage liver failure.

Transplant candidates shall meet all of the following general criteria:

- a. Adequate cardiopulmonary status;
- b. Absence of significant infection that could be exacerbated by immunosuppressive therapy (e.g., chronic active viral hepatitis B, hepatitis C, and human immunodeficiency virus);
- c. No active, potentially life-threatening, malignancy;
- d. Documentation of beneficiary compliance with medical management; and
- e. Beneficiary and caregiver are willing and capable of following the post transplant treatment plan.

Small Bowel Specific: Intestinal failure results from surgical resection, congenital defect, or disease-associated loss of absorption and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance. Short-bowel syndrome is one case of intestinal failure.

Small Bowel/Liver Specific: Evidence of intolerance of TPN includes multiple and prolonged hospitalizations to treat TPN-related complications, or the development of progressive but reversible liver failure. In the setting of progressive liver failure, small bowel transplant may be considered a technique to avoid end-stage liver failure related to chronic TPN, thus avoiding the necessity of a multivisceral transplant.

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 Medicaid Beneficiaries 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 small bowel, small bowel/liver, or multivisceral transplant for:

- a. adults who are able to tolerate TPN;
- b. human organ transplant (HOT) services, for which the cost is covered or funded by governmental, foundation, or charitable grants; and
- c. organs that are sold rather than donated to a beneficiary.

4.2.2 Psychosocial History

Small bowel, small bowel/liver, or multivisceral transplantation is not covered 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

Small bowel, small bowel/liver, or multivisceral transplant is not covered 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 shall not cover pancreas transplantation

- a. when the beneficiary has an active substance use; or
- b. for beneficiaries with a recent history of substance use, where there is no documentation of
 1. a completed substance abuse or therapy program; plus
 2. six months of negative sequential random drug screens.

4.2.5 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 Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid shall not require prior approval for small bowel, small bowel/liver, or multivisceral transplants.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

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 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 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).
- c. FDA approved procedures, products, and devices for implantation must be utilized for small bowel, small bowel/liver, or multivisceral transplants.
- d. Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.
- e. 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: June 6, 1994

Revision Information:

Date	Section Revised	Change
07/01/2005	Throughout	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.
12/01/2005	Sections 2.2	The special provision related to EPSDT was revised.
12/01/2005	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	NCHC policy developed comparable to DMA Clinical Coverage Policy 11B-8
12/01/2011	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.
03/12/2012	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11B-8 under Session Law 2011-145, § 10.41.(b)
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."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/06/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on

Date	Section Revised	Change
		or after implementation, please contact your PHP.”
01/06/2020	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.
07/01/2021	Section 5.0	Prior approval requirement removed.
07/01/2021	Attachment A	Added claim type Institutional (UB-04/83711). Removed specific ICD-10 PCS and CPT codes. Removed prior approval language from 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/>

I. Billing for Donor Expenses

1. Billing for Donor Expenses for Medicaid Beneficiaries

Donor transplant-related medical expenses are billed on the Medicaid beneficiary's transplant claim using the beneficiary's Medicaid identification number. Medicaid reimburses only for the actual donor's transplant-related medical expenses. Medicaid does not reimburse for unsuccessful donor searches.

2. Cadaveric/Deceased Organ Donations

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a small bowel, small bowel/liver or multivisceral transplant.

5. Living Organ Donations for a Medicaid Beneficiary

Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for an adult-to-child split liver transplant. Medicaid only covers reimbursement for the approved donor.