

Table of Contents

1.0 Description of the Procedure, Product, or Service..... 1

2.0 Eligible Recipients 1

 2.1 General Provisions 1

 2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age 1

3.0 When the Procedure, Product, or Service Is Covered..... 2

 3.1 General Criteria..... 3

 3.2 Specific Criteria 3

4.0 When the Procedure, Product, or Service Is Not Covered..... 4

 4.1 General Criteria..... 4

 4.2 Specific Criteria 4

 4.3 Psychosocial History..... 4

 4.4 Medical Compliance 4

 4.5 Substance Abuse 4

5.0 Requirements for and Limitations on Coverage 5

 5.1 Prior Approval 5

 5.2 Prior approval requirements..... 5

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 5

7.0 Additional Requirements 5

 7.1 Compliance 6

8.0 Policy Implementation/Revision Information..... 6

Attachment A: Claims-Related Information 7

 A. Claim Type 7

 B. Diagnosis Codes 7

 C. Procedure Code(s)..... 7

 D. Modifiers..... 7

 E. Billing Units..... 7

 F. Place of Service 7

 G. Co-payments 7

 H. Reimbursement 7

 I. Billing for Donor Expenses 8

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 recipients 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 recipients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become dependent on total parenteral nutrition (TPN). Recipients 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 recipients 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.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category, that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

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 recipients 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 clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

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

- a. that is unsafe, ineffective, or experimental/investigational.
- b. 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/or 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 will correct or improve or maintain the recipient'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**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

3.0 When the Procedure, Product, or Service Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

3.1 General Criteria

Medicaid covers procedures, products, and services related to this policy when they are 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 recipient'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 recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Medicaid covers small bowel transplant using a cadaveric intestine when medically necessary in adult or pediatric recipients 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 recipient 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 recipients 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 recipient compliance with medical management; and
- e. Recipient 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.

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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily 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

Medicaid does 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 recipient.

4.3 Psychosocial History

Small bowel, small bowel/liver, or multivisceral transplantation is not covered when the recipient's psychosocial history limits the recipient's ability to comply with pre- and post-transplant medical care.

4.4 Medical Compliance

Current recipient or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

4.5 Substance Abuse

Small bowel, small bowel/liver, or multivisceral transplantation is not covered when the recipient has an active substance abuse or, for recipients with a recent history of substance abuse, there is no documentation of the completion of a substance abuse or therapy program plus six months of negative sequential random drug screens.

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

5.1 Prior Approval

Prior approval is required for small bowel, small bowel with liver, or multivisceral transplant.

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

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

5.2 Prior approval requirements

Refer to *Basic Medicaid Billing Guide, section 6:*
<http://www.ncdhhs.gov/dma/basicmed/>

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet Medicaid's qualifications for participation;
- b. be currently enrolled with N.C. Medicaid; 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.

7.0 Additional Requirements

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

FDA approved procedures, products, and devices for implantation must be utilized for small bowel, small bowel with liver, or multivisceral transplants.

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 recipient'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
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
12/1/11	Entire Policy	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code(s)	Description
44132	Donor enterectomy(including cold preservation), open; from cadaver donor
44133	Donor enterectomy(including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete
47133	Donor hepatectomy from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47136	Liver allotransplantation; heterotopic, partial or while, from cadaver or living donor, any age

ICD-9 Code(s)	Description
46.97	Transplant of intestine
50.59	Other transplant of liver

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

One unit per day

F. Place of Service

Acute inpatient hospital

G. Co-payments

Co-payments are not required for small bowel, small bowel with Liver or multivisceral transplants.

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses for non-Medicaid donors are billed on the Medicaid recipient's transplant claim using the recipient's Medicaid identification number. Donor expenses for Medicaid donors are billed on the Medicaid donor's claim using the donor's Medicaid identification number.

Medicaid reimburses only for the actual donor's expenses. Medicaid does not reimburse for unsuccessful donor searches.

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 if the transplant recipient has received prior approval for a cadaveric/deceased organ transplant procedure.

Living Organ Donations:

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a small bowel transplant if the transplant recipient has received prior approval for a living organ transplant procedure. Medicaid only covers reimbursement for the approved donor.