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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 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. 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

To be eligible, NC Health Choice (NCHC) recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC 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; **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

NCHC covers small bowel transplant using a cadaveric intestine when medically necessary in 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.

NCHC 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.

NCHC covers small bowel/liver transplant or multivisceral transplant when medically necessary in 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

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 or investigational, or part of a clinical trial.

4.2 Specific Criteria

NCHC does not cover small bowel, small bowel/liver, or multivisceral transplant for:

- a. human organ transplant (HOT) services, for which the cost is covered or funded by governmental, foundation, or charitable grants; and
- b. 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 ~~and~~/or therapy program plus six months of negative sequential random drug screens.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

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

All applicable NCHC 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

The provider(s) shall submit to DMA's designee the following:

- a. the prior approval request; and
- b. all health care records and any other records that support the NCHC recipient has met the specific criteria in **Subsection 3.2** of this policy.

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 NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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

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: July 1, 2010

Revision Information:

Date	Section Revised	Change
7/1/10		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
12/1/11	Throughout	NCHC policy developed comparable to DMA Clinical Coverage Policy 11B-8

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

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-payment(s) may apply to covered prescription drugs and services

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

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

NCHC reimburses only for the actual donor's expenses. NCHC 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 an adult-to-child split liver transplant if the transplant recipient has received prior approval for a living organ transplant procedure. NCHC only covers reimbursement for the approved donor.