02-40000-18 Original Effective Date: 07/15/02 Reviewed: 06/26/25

Revised: 07/15/25

Subject: Isolated Small Bowel Transplant

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

A small bowel transplant may be performed as an isolated procedure or in conjunction with other visceral organs, including the liver, duodenum, jejunum, ileum, pancreas, or colon. Isolated small bowel transplant is commonly performed in individuals 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 atresias are predominant causes.

POSITION STATEMENT:

Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

- 1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
- 2. Complete all fields on the form thoroughly.
- 3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

A small bowel transplant using cadaveric intestine **meets the definition of medical necessity** in adult and pediatric individuals:

- With intestinal failure (characterized by loss of absorption and the inability to maintain proteinenergy, fluid, electrolyte, or micronutrient balance), **AND**
- Established long-term dependency on total parenteral nutrition (TPN) and are developing or have developed severe complications due to TPN, including but not limited to:
 - Multiple prolonged hospitalizations to treat TPN-related complications (e.g., repeated episodes of catheter-related sepsis)
 - Development of progressive liver failure [in those receiving TPN, liver disease with jaundice (total bilirubin above 3 mg/dL) is often associated with development of irreversible progressive liver disease]
 - Inability to maintain venous access

A small bowel transplant using a living donor **meets the definition of medical necessity** only when a cadaveric intestine is not available for transplantation in a candidate who meets the criteria noted above for a cadaveric intestinal transplant. A small bowel transplant using living donors **does not meet the definition of medical necessity** in all other situations.

A small bowel retransplant **meets the definition of medical necessity** after a failed primary small bowel transplant.

A small bowel transplant **does not meet the definition of medical necessity** for adults and children with intestinal failure who are able to tolerate TPN.

Potential contraindications to isolated small bowel transplant (subject to the judgment of the transplant center) include:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to intestinal failure
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

BILLING/CODING INFORMATION:

CPT Coding:

44132	Donor enterectomy (including cold preservation), open, from cadaver donor (non-covered
	by Medicare)
44133	Donor enterectomy, open, with preparation and maintenance of allograft; partial, from
	living donor
44135	Intestinal allotransplantation; from cadaver donor

44136	Intestinal allotransplantation; from living donor
44715	Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein
44720	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation, venous anastomosis, each
44721	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation, arterial anastomosis, each

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Intestinal and Multi-Visceral Transplantation (260.5), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <u>Coverage</u> <u>Protocol Exemption Request</u>

DEFINITIONS:

Congenital atresia: obstruction or closure of an orifice or tubular organ (i.e., intestine).

Enterectomy: excision of a part of the intestine; resection of the intestine.

Enterocolitis: inflammation involving the small intestine and colon.

Gastroschisis: a congenital fissure of the abdominal wall not involving the site of insertion of the umbilical cord, and usually accompanied by protrusion of the small intestine and part of the large intestine.

Necrotizing: changes indicative of cell death caused by progressive deteriorating action of enzymes, affecting groups of cells or part of a structure or organ.

Total parenteral nutrition: percutaneous transvenous infusion of a nutritionally adequate hypertonic solution consisting of glucose (sugar), amino acids (protein), electrolytes (sodium, potassium), vitamins and minerals, and sometimes fats.

Volvulus: intestinal obstruction due to knotting or twisting of the bowel.

RELATED GUIDELINES:

Liver Transplant and Combined Liver-Kidney Transplant, 02-40000-20

Small Bowel, Liver and Multivisceral Transplant, 02-40000-19

OTHER:

Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

Florida Statute 627.64197 Coverage for organ transplants. —A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 627.65736 Coverage for organ transplants. —A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 641.31075 Coverage for organ transplants. —A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/26/25.

GUIDELINE UPDATE INFORMATION:

07/15/01	Medical Coverage Guideline reformatted.		
03/15/02	Medical Coverage Guideline reviewed – no changes.		
04/15/03	Reviewed; no changes.		
04/15/04	Scheduled review; added investigational statement for small bowel transplants in HIV-		
	positive recipients; formatting changes.		
01/01/05	HCPCS coding update: added 44137, 44715, 44720, and 44721.		
04/15/05	Scheduled review; no change in coverage statement.		
06/15/05	Revision of guideline, consisting of removal of investigational statement regarding HIV-		
	positive recipients.		
06/15/06	Scheduled review; no change in coverage statement.		
06/15/07	Scheduled review; reformatted guideline; updated references.		
07/15/08	Scheduled review; add intestinal failure language to position statement. Update		
	references.		
07/15/09	Scheduled review; no change in position statement. Update references.		
07/15/10	Annual review: position statements maintained and references updated.		
10/15/10	Revision; related ICD-10 codes added.		
07/15/14	Scheduled review. Revised MCG title, description, position statement, CPT coding,		
	program exceptions, and definitions. Updated references.		
12/15/19	Scheduled review. Revised description, maintained position statement, and updated		
	references.		
07/01/20	Revision: added Florida statute language regarding discrimination in access to		
	anatomical gifts and coverage of organ transplants. Updated references.		
09/15/21	Scheduled review. Maintained position statement and updated references.		
05/25/23	Update to Program Exceptions section.		
09/15/23	Scheduled review. Maintained position statement and updated references.		
07/15/25	Scheduled review. Maintained position statement and updated references.		