INTESTINAL TRANSPLANTATION

Policy Number: 2016M0066B  Effective Date: November 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This policy describes the use of intestinal small bowel transplantation, as a therapeutic option for selected patients with irreversible intestinal failure and complications from or inability to tolerate total parenteral nutrition (TPN). Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome (SBS). The purpose of small bowel transplantation is to restore intestinal function and eliminate or reduce the need for TPN.

The majority of the intestinal transplantation uses small bowel allografts from cadaveric donors. Although promising, routine use of living-related-donor intestinal transplants is not recommended because the net health outcome associated with this procedure is reduced (compared to cadaveric transplant), and has a high donor-related morbidity.

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### COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

#### Isolated Small Bowel Transplant

A. A small bowel transplant using a cadaveric intestine may be considered **MEDICALLY NECESSARY** in adult and pediatric patients with life threatening complications attributable to irreversible intestinal failure, associated with all of the following criteria:

1. Reduced gastrointestinal absorption resulting in the need for parenteral nutrition, **AND**
2. Long-term dependency (minimum of two years) on total parenteral nutrition (TPN), **AND**
3. Severe complications due to failed TPN (e.g., thrombosis of two or more major central venous channels, repeated central line-related sepsis, frequent episodes of severe dehydration).

B. A small bowel transplant using a living donor may be considered **MEDICALLY NECESSARY** only when a cadaveric intestine is not available for transplantation in a patient who meets the criteria noted above for a cadaveric intestinal transplant.

A small bowel transplant using living donors is considered **NOT MEDICALLY NECESSARY** in all other situations. The long-term outcomes of living intestine donors have not yet been reported.

C. A small bowel transplant is considered **INVESTIGATIONAL AND/OR EXPERIMENTAL** for adults with intestinal failure who are able to tolerate TPN.

#### Small Bowel/Liver Transplant

A. Small bowel / liver transplants using a cadaver donor may be considered **MEDICALLY NECESSARY** in pediatric and adult patients with short bowel syndrome (SBS) who meet all of the following:

1. Patient has irreversible small bowel failure; and
2. Patient has been managed with long-term TPN for a minimum of two years; and
3. There is evidence of impending end-stage liver failure such as:
   - Prolonged prothrombin time (PT) > 2 times the laboratory "control" value with normal range ordinarily 11 to 13.5 seconds; or
   - Decreasing albumin to < 3.0 with normal range ordinarily 3.4 to 5.4 g/dL; and
   - There is evidence of severe complications from TPN (e.g., liver dysfunction, repeated infections, thrombosis, difficult venous access for TPN or fluids)
Multivisceral Transplants

A. Simultaneous multi-visceral transplants (including small bowel and liver but can also include the stomach, duodenum, jejunum, ileum, pancreas, or colon), also known as cluster transplant, using a cadaver donor may be considered MEDICALLY NECESSARY in pediatric and adult patients with SBS who meet all of the following:

1. Patient meets the criteria above for isolated small bowel transplant, AND
2. Patient must have evidence of severe liver dysfunction
   - Prolonged prothrombin time (PT) > 2 times the laboratory "control" value with normal range ordinarily 11 to 13.5 seconds, OR
   - Decreasing albumin to < 3.0 with normal range ordinarily 3.4 to 5.4 g/dL, AND
3. Patient must have evidence other than small bowel problems such as pancreatic failure, thromboses of the celiac axis, and the superior mesenteric artery or pseudo-obstruction affecting the entire gastric and small bowel tract, AND
4. Patient must have tried or considered all other medically necessary medical and surgical therapies that might have been expected to yield both short and long-term survival comparable to that of transplantation, AND
5. Pediatric patient should have a parent or legal guardian who has a realistic understanding of the range of clinical outcomes that may be encountered, AND
6. Adult patients should also have a realistic understanding of the range of clinical outcomes that may be encountered, AND
7. Patient must have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.

B. Living donor intestinal or multivisceral transplantation for any indication is considered INVESTIGATIONAL AND/OR EXPERIMENTAL and NOT MEDICALLY NECESSARY.

Clinical Considerations:

- Adult causes: Crohn's disease, Superior mesenteric artery thrombosis, Superior mesenteric vein thrombosis, Trauma, Desmoid tumor requiring extensive resection, Volvulus, Gastroschisis, Small bowel secretory disorders (e.g., small bowel inclusion diseases), Pseudo-obstruction.
- Adaptation following disease or injury that leads to intestinal failure can occur over many months up to a year or more. The ability of the remaining gut to adapt to be able to support the patient with enteral nutrition alone is determined by a number of factors including the length of the remaining intestine, the segments remaining, the presence of an ileocecal valve, the presence or absence of the colon and general motility patterns. A number of medical and surgical interventions are possible to help many of these patients avoid transplant.
- Total parenteral nutrition entails the administration of micronutrients and macronutrients via catheters in central or peripheral veins. In most cases, the central venous route is used. For long-term TPN, a central catheter (e.g., Hickman, Broviac, and PIC) is placed subcutaneously in the anterior chest.
Indicators of failed TPN are loss or impending loss of central venous access (e.g., thrombosis), recurrent systemic sepsis, and frequent episodes of dehydration. Additional life-threatening indications include severe short bowel syndrome, frequent hospitalization, or pseudo-obstruction.

- Patients with intestinal failure syndromes should be managed in centers with robust intestinal failure/rehabilitation programs to take advantage of all opportunities to regain adequate function and to avoid total parenteral nutrition (TPN) with its complications and intestinal transplantation.
- Timelier referral of intestinal failure patients who have not yet developed end-stage liver disease may allow for an intestine only transplant (IOT), which is associated with better outcomes.
- The evidence supports the fact that aged patients generally do not survive as well as younger patients receiving intestinal transplantation. Nonetheless, some older patients who are free from other contraindications have received the procedure and are progressing well, as evidenced by the United Network for Organ Sharing (UNOS) data. Thus, it is not appropriate to include an age limitation as a contraindication.

**Contraindications:**

Contraindications for intestinal and multivisceral transplantation are similar to those for other types of solid organ transplantation.

- Ongoing alcohol abuse and substance abuse.
- Active malignancy that is expected to significantly limit future survival.
- Persistent, recurrent or unsuccessfully treated major or systemic infections.
- Systemic illness or comorbidities that would be expected to substantially and negatively impact the successful completion and/or outcome of transplant surgery, such as, but not limited to:
  - Severe end stage organ damage including: Severe diabetes mellitus with end organ damage, irreversible severe pulmonary disease, with FEV1 <1 L or FVC <50%, irreversible severe hepatic disease, irreversible severe renal disease
  - Advanced neurological disorders (e.g., neuroaxonal dystrophy, Tay-Sachs disease, Niemann-Pick disease and its variants, neuronal ceroid lipofuscinosis, and Huntington disease)
  - Encephalopathy with evidence of irreversible brain damage
  - Limited cognitive ability (memory loss, dementia, etc.)
- A pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure.
- Human immunodeficiency virus (HIV) disease unless all of the following are noted:
  - Cluster determinant (CD)4 count >200 cells/mm3,
  - HIV-1 ribonucleic acid (RNA) undetectable,
  - Stable antiretroviral therapy for more than three months, and
  - Absence of serious complications associated with HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; or resistant fungal infections; or Kaposi’s sarcoma or other neoplasm).
- Hepatitis B surface antigen positive (HBSAg+) or Hepatitis C positive.
- Active systemic illness that is likely to negatively affect survival.
BACKGROUND:

Intestinal small bowel, liver-intestinal, or multivisceral transplantation are accepted therapeutic options for highly selected individuals with irreversible intestinal and/or multivisceral organ failure who have failure, contraindication, or intolerance to total parenteral nutrition (TPN). Irreversible gastrointestinal system failure is defined as the inability to maintain nutrition or adequate fluid and electrolyte balance without special support, when currently available medical and surgical treatments fail to improve intestinal adaptation and gut function. Causes may differ among children and adults.

Although TPN is the standard of care for patients with temporary or permanent intestinal failure, it severely affects quality of life and may be associated with a number of highly morbid and sometimes fatal complications and has a treatment-related mortality of 7–28%. Transplantation should be considered once it has been clearly shown that the bowel cannot adapt to allow full enteral autonomy from parenteral nutrition. Additional life-threatening indications include impending or overt liver failure, loss or impending loss of central venous access (e.g., thrombosis), recurrent, systemic sepsis, frequent episodes of dehydration, high risk of death, severe short bowel syndrome, frequent hospitalization, or pseudo-obstruction.

Common Indications for Intestinal and Multivisceral Transplantation include:

- **Children**: Aganglionosis (Hirschsprung’s disease), Autoimmune enteropathy, Congenital epithelial mucosal disease (microvillus inclusion disease, tufting enteropathy), Familial polyposis, Gastrochisis, Inflammatory pseudotumor, Intestinal atresia, Intestinal failure-associated liver disease, Intestinal pseudo-obstruction, Microvillus inclusion disease, Necrotizing enterocolitis, Pseudo-obstruction, Radiation enteritis, Short gut syndrome, Tufting enteropathy, Trauma, Volvulus.

- **Adults**: Autoimmune enteritis, Crohn’s disease, Desmoid tumors, Gardner’s syndrome/familial polyposis, Hollow visceral myopathy, Inflammatory bowel disease, Ischemia, Radiation enteritis, Secretory diarrhea, Short gut syndrome, Surgical adhesions, Trauma, Vascular occlusion, Volvulus.

Intestinal and multivisceral transplantations are more challenging than other types of solid organ transplantation due to the intestine’s large number of immune competent cells and colonization of the gut with microorganisms. Intestinal allografts may be transplanted alone, as in an isolated intestine graft, or as a composite graft which may include the liver, duodenum, and pancreas. If the recipient operation includes replacement of the entire gastrointestinal graft, and liver it is generally referred to as a multivisceral transplantation. The type and number of transplanted organs is dictated by the extent of the abdominal pathology and the functional status of the organs at the time of transplantation.

Isolated intestine transplantation may be indicated when there is a permanent need for total parenteral nutrition (TPN) after failure of intestinal adaptation, and attempts of medical and surgical rehabilitation (Matarese, 2006). Combined liver-intestinal transplantation may be appropriate for individuals with combined intestinal and TPN-associated liver failure, liver failure associated with portal and mesenteric venous thrombosis, intestinal failure due to a hypercoagulable state associated with enzyme deficiencies that can be corrected by a liver graft (e.g., mesenteric vascular thrombosis secondary to protein C or S deficiency), or documented end-stage hepatic disease. In adults, such disease is associated with refractory ascites, spontaneous bacterial peritonitis, refractory variceal bleeding, chronic encephalopathy, hepatorenal syndrome, failure to thrive, or a severe compromise in the quality of life (Abu-Elmagd, 2001).
In children, end-stage hepatic disease is suggested by hyperbilirubinemia persisting beyond three to four months of age, combined with features of portal hypertension, such as splenomegaly, thrombocytopenia, or prominent superficial abdominal veins.

A full multivisceral transplantation involves the en bloc transplantation of the stomach, liver, duodenum and pancreas with the intestine. In a modified procedure only one or two organs may be transplanted. It is indicated for patients with irreversible failure of their abdominal visceral organs, including the small bowel. The aims of multivisceral transplantation are to replace as many functional digestive units as possible, restore gastric emptying, ileocecal valve function, rectal continence, and improvement of surgical and oncological margins of resection (Braun, 2007). Conditions include symptomatic extensive thrombosis of the splanchnic vascular system, massive gastrointestinal polyposis or neoplasm, and generalized hollow visceral myopathy or neuropathy (Abu-Elmagd, 2001). Multivisceral transplantation may also be indicated for diffuse gastrointestinal disorders such as dysmotility syndromes, hereditary neoplasms, and extensive vascular thrombosis (Matarese, 2006). According to Organ Procurement and Transplant Network annual report data (2011), almost 50% of deceased donor intestines were transplanted with another organ in 2011. In 2011, the organ was most commonly transplanted with the pancreas.

The hospitalization status of the intestinal transplant recipient at the time of transplantation remains a strong prognostic factor for patient survival, with an unadjusted 1-year survival rate of 83 percent for recipients not waiting in the hospital, 73 percent for recipients waiting in the hospital, and only 50 percent for recipients waiting in the intensive care unit (SRTR data base).

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
   Small bowel transplant from living donors for intestinal failure is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, biologics, drugs, or tests used as a part of this procedure may be subject to FDA regulation.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
   National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation (260.5) 

   Overview
   Multi-visceral and intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure are covered by Medicare. Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. It may be associated with both profound morbidity and mortality. Multi-visceral transplantation includes organs in the digestive system (pancreas, liver, stomach, duodenum, and intestine).

   The evidence supports the fact that aged patients generally do not survive as well as younger patients receiving intestinal transplantation. Some older patients who are free from other contraindications have received the procedure and are progressing well, as evidenced by the United Network for Organ
Sharing (UNOS) data. Thus, it is not appropriate to include specific exclusions from coverage, such as an age limitation, in the national coverage policy.

Guidelines

Nationally Covered Indications
This procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.

Failed TPN
The TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. TPN failure includes the following:

- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, Superior Vena Cava syndrome, pulmonary embolism, or chronic venous insufficiency.
- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, gastroesophageal varices, splenomegaly, thrombocytopenia, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.
- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.
- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.

Approved Transplant Facilities
Intestinal transplantation is covered by Medicare if performed in an approved facility. The criteria for approval of centers will be based on a volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent using the Kaplan-Meier technique.

Approved Facilities found at CMS.gov under Survey & Certification - Certification & Compliance

Nationally Non-covered Indications
All other indications remain non-covered.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
MHCP coverage for organ and tissue transplant procedures is limited to those procedures covered by the Medicare program or approved by the DHS consulting contractor. Transplant coverage includes: preoperative evaluation, recipient and donor surgery, follow-up care for the recipient and live donor, and retrieval of organs, tissues. All transplant related services are billed
under the recipient’s ID number.

**CLINICAL EVIDENCE:**

**SUMMARY:**

Although randomized controlled trial data are lacking, published consensus guidelines and peer-reviewed scientific literature support deceased donor intestinal and multivisceral transplantation as and accepted treatment for highly selected individuals. Based on the evidence reviewed, small bowel transplant may be considered medically necessary in patients with intestinal failure who are developing severe TPN-related complications, to obviate the subsequent need for a multivisceral transplant. Small bowel transplantation using a living donor may be considered medically necessary only when a cadaveric intestinal transplant is not available. Although promising, routine use of living-donor intestinal transplants is considered not medically necessary because the net health outcome associated with this procedure is reduced (compared to cadaveric transplant), and because of the donor-related morbidity. Repeat intestinal or multivisceral transplantation may be appropriate for an individual who meets eligibility criteria for primary transplantation.

**APPLICABLE CODES:**

*The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.*

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<tr>
<td>S2053</td>
<td>Transplantation of small intestine and liver allografts</td>
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<td>S2054</td>
<td>Transplantation of multivisceral organs</td>
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<td>Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor</td>
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<td>S2152</td>
<td>Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre-and post-transplant care in the global definition</td>
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### CPT® Codes

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<td>55133</td>
<td>Donor enterectomy (including cold preservation), open; partial, from living donor</td>
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<tr>
<td>44135</td>
<td>Intestinal allotransplantation; from cadaver donor</td>
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<td>44136</td>
<td>Intestinal allotransplantation; from living donor</td>
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<td>44137</td>
<td>Removal of transplanted intestinal allograft, complete</td>
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<td>44140</td>
<td>Colectomy, partial; with anastomosis</td>
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<td>44715</td>
<td>Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein</td>
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<td>44720</td>
<td>Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each</td>
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<td>44721</td>
<td>Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each</td>
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<td>Donor hepatectomy (including cold preservation), from cadaver donor</td>
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<td>47136</td>
<td>Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age</td>
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Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split

Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (i.e., left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII))

Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe (segments I, V-VIII))

Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each

Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each

Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation

Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery

Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each

Transplantation of pancreatic allograft

CPT® is a registered trademark of the American Medical Association.

REFERENCES:


33.


**POLICY HISTORY:**

<table>
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<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tr>
<td>06/03/2014</td>
<td>New Policy Number 2014D0066A. Reviewed and approved by the Interim Medical Policy Committee.</td>
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<tr>
<td>08/28/2014</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
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