



**Kaiser Foundation Health Plan  
of Washington**

***Clinical Review Criteria***  
**Intestinal and Multi-Visceral Transplantation**

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Intestinal and Multi-Visceral Transplantation (260.5)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

**For Non-Medicare Members**

- I. Intestinal and multi-visceral (stomach, duodenum, pancreas, liver, intestine, and colon) transplantation are a covered service for patients who meet **ALL of the following**:
  - A. Irreversible intestinal failure as defined by loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome.
  - B. Failed total parenteral nutrition (TPN). Defined as:
    1. Impending or overt liver failure due to TPN induced liver injury as defined by one of the following:
      - a) elevated bilirubin and/or liver enzymes
      - b) splenomegaly
      - c) thrombocytopenia
      - d) gastroesophageal varices
      - e) coagulopathy
      - f) stomal bleeding
      - g) hepatic fibrosis/cirrhosis
    2. Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins as defined by one of the following:
      - a) Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy
      - b) The sequelae of central venous thrombosis is a lack of access for TPN, fatal sepsis due to infected thrombi, pulmonary thrombosis, superior vena cava syndrome, or chronic venous insufficiency
    3. Frequent line infections and sepsis as defined as:
      - a) Two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization
      - b) A single episode of line related fungemia, septic shock and/or acute respiratory distress syndrome
    4. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN
      - a) Is performed in approved centers that have a volume of 10 intestinal transplants per year with a one-year actuarial survival rate of 65% using the Kaplan-Meier technique.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

**Background**

Intestinal transplantation is an evolving procedure that was experimentally developed more than 30 years ago. It involves transplantation of a cadaveric intestinal allograft for the purpose of restoring bowel function for patients with irreversible failure. The intestine's massive lymphocyte content and heavy bacterial load provided barriers for nearly three decades. Intestines are more susceptible to rejection, and carry higher risk of graft versus host disease (GVHD). The procedure proved to be clinically feasible for humans in the late 1980s, but had considerable morbidity and mortality. The initial recipients of the intestinal grafts did poorly because of technical complications, graft rejection and sepsis. Recently better results were reported due to improved surgical techniques, more potent immunosuppressive drugs, and standard prophylaxis for infections and lymphoproliferative disease. Although the purpose of intestinal transplantation is to restore bowel function, patient survival should be considered the primary outcome of interest.

The first long-term success was reported in 1988 when cyclosporin-based immunosuppression was used, yet there were many failures due to rejection. The introduction of FK 506 or Tacrolimus, have led to an explosion of the intestinal transplantation activity in the 1990s. It is 100 times more potent than cyclosporin and is somewhat less toxic. Steroids are administered during the early postoperative period, and discontinued completely within a month. Since 1990 surgeons at the University of Pittsburgh Medical Center (UPMC) and Children's Hospital of Pittsburgh have performed more than 115 transplants involving the small intestine. This is close to half the total number performed worldwide.

There are three types for intestinal transplantation: small bowel transplantation (SBT), Small bowel/liver transplantation (SB/LT), and multivisceral transplantation (MVT) which is defined as en-bloc transplantation of 3 or more abdominal organs that include liver, stomach, pancreatic-duodenal complexes as well as the intestine with or without the right hemi-colon. Intestinal transplantation is not an alternative to total parenteral nutrition (TPN), but is only intended for selected patients who are predicted to have poor survival on TPN. It should be considered as a life-saving procedure. Patients who can be maintained on long term TPN are not considered for transplantation at the present time.

An isolated intestinal graft is recommended for patients who have fluid and electrolyte loss that cannot be managed by TPN, those with severely limited venous access and/or moderate liver dysfunction secondary to TPN. Combined SB/LT is offered to patients with irreversible liver failure due to TPN, or intestinal/liver failure associated with a hyper-coagulable state that is corrected by a simultaneous liver graft. Multivisceral transplantation is offered to patients with locally aggressive tumors that can only be removed by a massive evisceration of the abdominal organs. Intestinal transplantation is contraindicated in old age, cardiopulmonary deficiency, AIDS, systemic malignancy and life threatening infections.

The FDA does not regulate surgical procedures such as intestinal and multivisceral transplantation. However, immunosuppressive drugs are FDA regulated. Tacrolimus, the primary immuno-suppressant used with these transplants was approved by the FDA in April 1994 for rejection prophylaxis in allogenic liver transplantation.

## Medical Technology Assessment Committee (MTAC)

### *Intestinal Transplantation*

#### **04/10/2002: MTAC REVIEW**

**Evidence Conclusion:** The literature reviewed did not reveal any study that compared intestinal transplantation to the long term TPN therapy, and the evidence available does not allow for definitive conclusions. The studies reviewed show that the one- year survival rate of intestinal transplantation varied among studies from 54% to 75%. This dropped to around 42-50% at 5 years. Infection was responsible for more than 40% of the deaths. All studies were case series with limitations including potential selection bias, and lack of control or comparison group. However, it is unlikely that controlled trials, in which outcomes from intestinal/multivisceral transplantation are compared to TPN and medical management, would be conducted. The current use of intestinal transplantation as a rescue therapy for TPN-dependant patients invalidates any comparison with TPN.

**Articles:** Articles were selected based on study type. The search yielded 175 articles most of which were reviews, opinion pieces, editorials, and letters. The literature did not reveal any randomized controlled trials, or meta-analyses, only clinical reports and case series. The articles with the largest size, longest follow-up duration, and with patient survival as the primary outcome of interest were selected for critical appraisal. *Evidence tables were created for the following case series:* Abu-Elmagd K, et al. Clinical intestinal transplantation. *Annals of Surgery* 2001;234(3):404-17. See [Evidence Table](#) Jamieson NV. Adult small intestine transplantation in Europe. *Acta Gastro- Enterologica Belgica* 1999;62(2):239-43. See [Evidence Table](#) Madariaga JR, et al. The long-term efficacy of multivisceral transplantation. *Transplantation proceedings* 2000;32:1219-20. See [Evidence Table](#).

The use of Intestinal Transplantation in the treatment of irreversible intestinal failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
05/30/2001	04/06/2010 <sup>MDCRPC</sup> , 02/10/2011 <sup>MDCRPC</sup> , 12/06/2011 <sup>MDCRPC</sup> , 10/02/2012 <sup>MDCRPC</sup> , 08/06/2013 <sup>MPC</sup> , 06/03/2014 <sup>MPC</sup> , 04/07/2015 <sup>MPC</sup> , 02/02/2016 <sup>MPC</sup> , 12/06/2016 <sup>MPC</sup> , 10/03/2017 <sup>MPC</sup> , 08/07/2018 <sup>MPC</sup>	10/13/2006

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Policy Committee

Revision History	Description

### Codes

CPT: 44135; 44136; 44137