

Corporate Medical Policy

Small Bowel, Small Bowel with Liver, or Multivisceral Transplant

File Name: small_bowel_liver_and_multivisceral_transplant
Origination: 2/1996
Last CAP Review: 5/2020
Next CAP 5/2021
Last Review: 5/2020

Description of Procedure 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.

Short bowel syndrome 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 micronutrient uptake in the remaining small bowel. Pharmacologic agents have been studied to increase villous proliferation and slow transit times, and surgical techniques have been advocated to optimize remaining small bowel. Some patients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become dependent on total parenteral nutrition (TPN). Patients 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 total parenteral nutrition (TPN). These patients 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, and/or colon. A multivisceral transplant is indicated when anatomic or other medical problems preclude a small bowel/liver transplant.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Small Bowel/Liver and/or Multivisceral Transplantation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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There may be certificates which specifically exclude benefits for transplantation or for specific diagnoses.

Coverage is not provided for organs sold rather than donated to the recipient.

When Small Bowel, Small Bowel with Liver, or Multivisceral Transplantation is covered

A.) **A small bowel transplant** using cadaveric intestine may be considered medically necessary in adult and pediatric patients 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 total parenteral nutrition (TPN) and are developing or have developed severe complications due to TPN.

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 for a cadaveric intestinal transplant.

A small bowel retransplant may be considered medically necessary after a failed primary small bowel transplant.

B.) **Small bowel/liver transplant** or multivisceral transplant may be considered medically necessary in pediatric and adult patients 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 TPN, and have developed evidence of impending end-stage liver failure.

C.) **A small bowel/liver retransplant or multivisceral retransplant** may be considered medically necessary after a failed primary small bowel/liver transplant or multivisceral transplant.

When Small Bowel, Small Bowel with Liver, or Multivisceral Transplantation is not covered

Small Bowel, Small Bowel with Liver, or Multivisceral Transplantation is considered not medically necessary when the criteria listed above have not been met.

A small bowel transplant is considered **investigational** for adult and pediatric patients with intestinal failure who are able to tolerate TPN.

Policy Guidelines

Cases requesting approval for transplants will be reviewed to determine medical necessity according to the Plan as outlined in this policy provided the certificate does not **exclude** benefits for Small Bowel Transplant, Small Bowel with Liver, or Multivisceral.

Refer to the individual certificate for prior review requirements.

It is recommended that all transplant requests be reviewed by the Plan Medical Director or his or her designee. Only those patients accepted for transplantation by a transplantation center and actively listed for transplant should be considered for review. Guidelines should be followed for transplant network or consortiums, if applicable.

Potential contraindications subject to the judgment of the transplant center:

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
3. Untreated systemic infection making immunosuppression unsafe, including chronic infection
4. Other irreversible end-stage disease not attributed to intestinal failure
5. History of cancer with a moderate risk of recurrence

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6. Systemic disease that could be exacerbated by immunosuppression
7. Psychosocial conditions or chemical dependency affecting the ability to adhere to therapy

Transplant candidates should meet the following general criteria:

- Adequate cardiopulmonary status,
- Absence of significant infection that could be exacerbated by immunosuppressive therapy ,
- No history of malignancy within 5 years of transplantation, excluding nonmelanomatous skin cancers,
- Documentation of patient compliance with medical management.

HIV (human immunodeficiency virus)-positive patients who meet the following criteria, as stated in the 2017. British HIV Association and the British Transplantation Society guidelines, could be considered candidates for small bowel/liver or multivisceral transplantation.

Current Organ Procurement and Transplantation policy permits HIV-positive transplant candidates.

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney transplantation in patients with HIV disease. These criteria may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy
- Cluster of differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- No opportunistic infections for at least 6 months
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

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.

Patients who are developing or have developed severe complications due to total parenteral nutrition (TPN) include, but are not limited to, the following: multiple and prolonged hospitalizations to treat TPN-related complications (especially repeated episodes of catheter-related sepsis) or the development of progressive 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. In those receiving TPN, liver disease with jaundice (total bilirubin above 3 mg/dL) is often associated with development of irreversible progressive liver disease. The inability to maintain venous access is another reason to consider small bowel transplant in those who are dependent on TPN.

Small Bowel/Liver Specific: Evidence of intolerance of TPN includes, but is not limited to, 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.

Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 44120, 44121, 44132, 44133, 44135, 44136, 44715, 44720, 44721, 44799, 47133, 47135, 47136, 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147, S2053, S2054, S2055, S2152

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual

TEC - 12/95

Medical Policy Advisory Group Review 3/99

BCBSA Medical Policy Reference Manual - 12/1/99

Specialty Matched Consultant Advisory Panel - 9/00

NivY, Mor E, Tzakis AG. Small bowel transplantation--a clinical review. *Am J Gastroenterol.* 1999 Nov;94(11):3126-30.

TEC Review. Vol 14, No. 9. July 1999.

Hakim NS, Papalois VE. Small Bowel Transplantation. *Int Surg.* 1999 Oct-Dec;84(4):313-7.

Medical Policy Advisory Group 10/2000

BCBSA Medical Policy Reference Manual, 12/15/00; 7.03.04

Specialty Matched Consultant Advisory Panel, 6/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 10/9/2003.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 2/25/2004.

Specialty Matched Consultant Advisory Panel - 5/2004

ECRI. (1998) Intestinal/liver transplantation or small bowel transplantation. TARGET database. Retrieved on 4/13/2004 from

http://www.target.ecri.org/summary/detail.aspx?doc_id=133&q+=small+bowel+transplant.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 4/1/2005.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 9/27/2005.

Specialty Matched Consultant Advisory Panel - 4/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 1/10/08.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 1/10/08.

Specialty Matched Consultant Advisory Panel - 4/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 3/12/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 8/13/09.

Senior Medical Director Review - 11/2009

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for Intestinal and Multi-Visceral Transplantation (260.5). Retrieved 11/04/2010 from:

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http://www.cms.gov/mcd/viewncd.asp?ncd_id=260.5&ncd_version=2&basket=ncd%3A260%2E5%3A2%3AIntestinal+and+Multi%2DVisceral+Transplantation

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 8/13/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 6/10/10

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 10/08/10

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 11/10/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 11/10/11

Specialty Matched Consultant Advisory Panel – 4/18/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 06/14/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 10/11/12

Specialty Matched Consultant Advisory Panel – 4/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 06/13/13

Center for Medicare and Medicaid Services. Intestinal and multi-visceral transplantation. Available online at: www.cms.gov. Last accessed August, 2013.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 10/10/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 12/12/13

Specialty Matched Consultant Advisory Panel – 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 5/22/14

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 6/12/14

Specialty Matched Consultant Advisory Panel – 5/2015

Medical Director review 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 5/21/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 6/11/15

Specialty Matched Consultant Advisory Panel – 5/2016

Medical Director review 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 12/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 12/2016

Medical Director review 12/2016

Specialty Matched Consultant Advisory Panel – 5/2017

Medical Director review 5/2017

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 8/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 8/2017

Specialty Matched Consultant Advisory Panel – 5/2018

Medical Director review 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 8/2018

Specialty Matched Consultant Advisory Panel 8/2018

Medical Director review 8/2018

Specialty Matched Consultant Advisory Panel 5/2019

Medical Director review 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.04, 9/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.05, 9/2019

Specialty Matched Consultant Advisory Panel 5/2020

Medical Director review 5/2020

Policy Implementation/Update Information

9/94	Evaluated: Association considers investigational
2/96	Revised: Considered eligible for coverage as outlined in policy.
3/99	Reaffirmed
9/99	Reformatted, Description of Procedure or service changed, Medical Term Definitions added, combined Small Bowel and Small Bowel/Liver and Multivisceral Transplantation.
10/00	Reviewed by Specialty Matched Consultant Advisory Panel. Criteria changed for transplant. Added covered indications for adults for small bowel transplant. Added covered indications for multivisceral transplant for pediatric and adult patients. System coding changes. Medical Policy Advisory Group review. No further change to criteria. Approve.
12/00	2001 CPT codes added; 44132, 44133, 44135, 44136. System coding changes.
2/01	Revised. Added indications for cadaver donors to what is covered. Indications for multivisceral transplants not added in 10/00. Added with this update. Title of policy changed to Small Bowel, Small Bowel with Liver, or Multivisceral Transplant.
6/02	Specialty Matched Consultant Advisory Panel. No changes. Approve. Codes S2050 and S2052 deleted from Billing and Coding Section of policy.
4/04	Benefits Application and Billing/Coding sections updated for consistency. Code S2152 added to Billing/Coding section of policy.

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- 6/10/04 Specialty Matched Consultant Advisory Panel review. No change to criteria. Removed CPT codes 44120 and 44121 because they do not apply. References added. Notification 6/10/04. Effective date 8/12/2004.
- 1/6/05 Codes 44715, 44720, 44721 added to Billing/Coding section of policy.
- 5/22/06 Specialty Matched Consultant Advisory Panel review 4/20/2006. Removed repeated statement regarding short bowel syndrome from "Description of Procedure or Service" section. Added reference to "small bowel with liver or multivisceral" in "Policy Guidelines" section. Also added statement indicating; "Refer to individual certificate for prior approval/precertification requirements." Added CPT codes 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147 as they relate to the policy. References added.
- 6/16/08 Specialty Matched Consultant Advisory Panel review 4/30/08. Replaced references to "short bowel syndrome" in the "When Covered" section A. and B to "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 total parenteral nutrition (TPN) and have developed severe complications due to total parenteral nutrition (TPN)". Added "D. Candidates for transplants addressed above should meet all of the following general criteria: 1. adequate cardiopulmonary status; and 2. absence of active infection; and 3. no history of malignancy within 5 years of transplantation, excluding nonmelanomatous skin cancers; and 4. documentation of patient compliance with medical management." and referenced "D" where appropriate. References added. (btw)
- 2/2/10 Revised "Description" section. Added information to the "When Covered" section to indicate; "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 for a cadaveric intestinal transplant." Removed that statement from the "When Not Covered" section. Changed wording related to "prior approval/precertification" to indicate "prior review" where applicable. Reviewed with Senior Medical Director 11/9/2009. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 12/7/10 Description section revised. Medical coverage criteria in the When Covered and When Not Covered sections was reformatted. General criteria for transplant candidates moved to the Policy Guidelines section. References updated. Medical Director review 11/12/10. (adn)
- 5/10/11 Updated Description section. No change to Policy Statement or medical criteria. Updated Policy Guidelines section. Specialty Matched Consultant Advisory Panel review 4/27/11. (adn)
- 5/1/12 Potential contraindications added to Policy Guidelines section. Criteria for transplantation for HIV-positive patients added to Policy Guidelines section. CPT codes 44120 and 44121 added to Billing Section. Specialty Matched Consultant Advisory Panel review 4/18/12. (sk)
- 11/27/12 Reference added. No change to Policy Statement. (sk)
- 4/30/13 References added. Added Small Bowel Specific information to Policy Guidelines. Specialty Matched Consultant Advisory Panel review 4/17/13. No change to Policy Statement. (sk)
- 10/1/13 References added. Added the following indication, "A small bowel/liver transplant or multivisceral retransplant may be considered medically necessary after a failed primary small bowel/liver transplant or multivisceral transplant." Medical Director review. (sk)
- 1/28/14 Reference added. No change to Policy Statement. (sk)
- 3/11/14 Reference added. Statement added that small bowel retransplant may be considered medically necessary after a failed primary small bowel transplant. (sk)
- 5/13/14 Specialty Matched Consultant Advisory Panel review 4/29/14. No change to Policy Statement. (sk)

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- 7/29/14 References added. Added “pediatric patients” to the statement “A small bowel transplant is considered investigational for adult and pediatric patients with intestinal failure who are able to tolerate TPN.” (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. Medical Director review 5/2015. Policy Statements remain unchanged. References added. (td)
- 7/28/15 References updated. (td)
- 12/30/15 Billing/Coding section updated to delete code 47136. (td)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. Medical Director review 5/2016. No changes to policy. (jd)
- 1/27/17 References updated. Medical Director review 12/2016. (jd)
- 6/30/17 Specialty Matched Consultant Advisory Panel 5/2017. Medical Director review 5/2017. (jd)
- 6/8/18 References updated. Specialty Matched Consultant Advisory Panel 5/2018. Medical Director review 5/2018. (jd)
- 9/27/18 Minor update to Description section. Policy guidelines extensively revised for patients with HIV disease. No change to policy intent. References updated. Medical Director review 8/2018. (jd)
- 5/28/19 Specialty Matched Consultant Advisory Panel 5/2019. Medical Director review 5/2019.(jd)
- 6/9/20 Specialty Matched Consultant Advisory Panel 5/2020. Medical Director review 5/2020.(jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.