

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy

Small Bowel/Liver and Multivisceral Transplant

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Information Pertaining to All Policies

Description

Policy History

Policy Number: 632

BCBSA Reference Number: 7.03.05

NCD/LCD: National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplant (260.5)

Related Policies

Isolated Small Bowel Transplant, #631

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

A small bowel/liver transplant or multivisceral transplant may be <u>MEDICALLY NECESSARY</u> for 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 long-term total parenteral nutrition (TPN) and who have developed evidence of impending end-stage liver failure.

A small bowel/liver retransplant or multivisceral retransplant may be <u>MEDICALLY NECESSARY</u> after a failed primary small bowel/liver transplant or multivisceral transplant.

In addition to the above information, we do not cover small bowel/liver transplant or multivisceral transplantation when any of the following conditions are present:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
 - Note: the assessment of risk of recurrence for a previously treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
 - o Other irreversible end-stage disease not attributed to intestinal failure
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Candidates should meet the following criteria:

• Adequate cardiopulmonary status

Documentation of patient compliance with medical management.

HIV [human immunodeficiency virus]-positive patients who meet the following criteria, as stated in the 2001 guidelines of the American Society of Transplantation, could be considered candidates for small bowel/liver or multivisceral transplantation:

- CD4 count greater than 200 cells per cubic millimeter for greater than 6 months
- HIV-1 RNA undetectable
- On stable anti-retroviral therapy >3 months
- No other complications from AIDS [acquired immune deficiency syndrome] (e.g., opportunistic
 infection, including aspergillus, tuberculosis, coccidiosis mycosis, resistant fungal infections, Kaposi's
 sarcoma, or other neoplasm), and meeting all other criteria for transplantation.

A small/bowel/liver transplant or multivisceral transplant is **INVESTIGATIONAL** in all other situations.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link(s) below.

National Coverage Determinations (NCDs)

National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplant (260.5)

Intestinal and multi-visceral transplants must take place in a Medicare-approved facility

Note: To review the specific NCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed **inpatient**.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

| | Outpatient |
|---------------------------------------|---|
| Commercial Managed Care (HMO and POS) | This procedure is performed in the inpatient setting. |
| Commercial PPO and Indemnity | This procedure is performed in the inpatient setting. |
| Medicare HMO Blue SM | This procedure is performed in the inpatient setting. |
| Medicare PPO Blue SM | This procedure is performed in the inpatient setting. |

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

| CPT codes: | Code Description |
|------------|--|
| 44135 | Intestinal allotransplantation; from cadaver donor |
| 44136 | Intestinal allotransplantation; from living donor |
| 47135 | Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any |
| | age |

HCPCS Codes

| HCPCS codes: | Code Description |
|--------------|---|
| S2053 | Transplantation of small intestine and liver allografts |
| S2054 | Transplantation of multivisceral organs |

ICD-10 Procedure Codes

| ICD-10-PCS procedure | |
|----------------------|--|
| codes: | Code Description |
| 0DY60Z0 | Transplantation of Stomach, Allogeneic, Open Approach |
| 0DY60Z1 | Transplantation of Stomach, Syngeneic, Open Approach |
| 0FYG0Z0 | Transplantation of Pancreas, Allogeneic, Open Approach |
| 0FYG0Z1 | Transplantation of Pancreas, Syngeneic, Open Approach |
| 0DY80Z0 | Transplantation of Small Intestine, Allogeneic, Open Approach |
| 0DY80Z1 | Transplantation of Small Intestine, Syngeneic, Open Approach |
| 0FY00Z1 | Transplantation of Liver, Syngeneic, Open Approach |
| 0FY00Z0 | Transplantation of Liver, Allogeneic, Open Approach |
| 0DT80ZZ | Resection of Small Intestine, Open Approach |
| 0DT84ZZ | Resection of Small Intestine, Percutaneous Endoscopic Approach |
| 0DYE0Z0 | Transplantation of Large Intestine, Allogeneic, Open Approach |
| 0DYE0Z1 | Transplantation of Large Intestine, Syngeneic, Open Approach |

Description

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life.¹ Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Small Bowel/Liver and Multivisceral Transplant

In 2019, 39,719 transplants were performed in the United States procured from almost 11,900 deceased donors and 7,400 living donors. Intestinal transplants occur less frequently than other organ transplants, with 10 or fewer patients receiving liver-intestine transplant each year from 2008 to 2019. https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/# Small bowel and liver or multivisceral transplant is usually considered in adults and children who develop serious complications related to parenteral nutrition, including inaccessibility (eg, due to thrombosis) of access sites, catheter-related sepsis, and cholestatic liver disease.

Short Bowel Syndrome

Short bowel syndrome is defined as an inadequate absorbing surface of the small intestine due to extensive disease or surgical removal of a large portion of the small intestine.² In some instances, short

bowel syndrome is associated with liver failure, often due to the long-term complications of total parenteral nutrition.

Treatment

A small bowel/liver transplant or a multivisceral transplant includes the small bowel and liver with 1 or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, and/or colon. The type of transplantation depends on the underlying etiology of intestinal failure, quality of native organs, presence or severity of liver disease, and history of prior abdominal surgeries.^{3,} A multivisceral transplant is indicated when anatomic or other medical problems preclude a small bowel/liver transplant. Complications following small bowel/liver and multivisceral transplants include acute or chronic rejection, donor-specific antibodies, infection, lymphoproliferative disorder, graft-versus-host disease, and renal dysfunction.^{4,}

Summary

This evidence review addresses transplantation and retransplantation of an intestinal allograft in combination with a liver allograft, either alone or in combination with one or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, or colon.

For individuals who have intestinal failure and evidence of impending end-stage liver failure who receive a small bowel and liver transplant alone or multivisceral transplant, the evidence includes a registry study and a limited number of case series. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. These transplant procedures are infrequently performed, and few reported case series exist. However, results from the available literature have revealed fairly high postprocedural survival rates. Given these results and the exceedingly poor survival rates of patients who exhaust all other treatments, transplantation may prove not only to be the last option but also a beneficial one. Transplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease, or in whom posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a failed small bowel and liver or multivisceral transplant without contraindications for retransplant who receive a small bowel and liver retransplant alone or multivisceral retransplant, the evidence includes case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Although limited in quantity, the available post retransplantation data have suggested reasonably high survival rates. Given exceedingly poor survival rates without retransplantation of patients who have exhausted other treatments, evidence of postoperative survival from uncontrolled studies is sufficient to demonstrate that retransplantation provides a survival benefit in appropriately selected patients. Retransplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History

| Date | Action |
|---------|--|
| 10/2020 | BCBSA National medical policy review. Description, summary, and references updated. Policy statement(s) unchanged. |
| 10/2019 | BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified. |
| 10/2018 | BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified. |
| 9/2017 | New references added from BCBSA National medical policy. |
| 1/2017 | New references added from BCBSA National medical policy. |
| 1/2016 | Clarified coding information. |

| 8/2015 | Coding information clarified. |
|----------|---|
| 10/2014 | Medical policy remediation: New indications for non-coverage. Coding information clarified. Effective 10/1/2014. |
| 4/2014 | Coding information clarified. |
| 12/2013 | BCBSA National medical policy review. New medically necessary indications described. Effective 12/1/2013. Coding information clarified. |
| 11/2011- | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No |
| 4/2012 | changes to policy statements. |
| 5/2012 | BCBSA National medical policy review. Changes to policy statements. |
| 11/2010 | Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ |
| | Transplantation. No changes to policy statements. |
| 10/2010 | BCBSA National medical policy review. No changes to policy statements. |
| 6/2010 | BCBSA National medical policy review. Changes to policy statements. |
| 11/2009 | BCBSA National medical policy review. Changes to policy statements. |
| 11/2009 | Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ |
| | Transplantation. No changes to policy statements. |
| 5/2009 | BCBSA National medical policy review. No changes to policy statements. |
| 11/2008 | Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

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 - details.aspx?NCDId=280&ncdver=2&CoverageSelection=National&KeyWord=intestinal&KeyWordLookUp=Title&
 - KeyWordSearchType=And&generalError=Thank+you+for+your+interest+in+the+Medicare+Coverage +Database.