BlueCross BlueShield of Louisiana

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Small Bowel Transplant, Small Bowel/Liver Transplant and Multivisceral Transplant

Policy # 00112
Original Effective Date: 01/28/2002
Current Effective Date: 08/20/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider small bowel/liver transplant or multivisceral transplant for pediatric and adult patients to be **eligible for coverage**.

Patient Selection Criteria
Coverage eligibility will be considered for pediatric and adult patients with intestinal failure when all of the following criteria are met:

- Have intestinal failure; and
- Have been managed with long-term total parenteral nutrition (TPN); and
- Have developed evidence of impending end-stage liver failure.

Based on review of available data, the Company may consider a small bowel/liver retransplant or multivisceral retransplant after a failed primary small bowel/liver transplant or multivisceral transplant to be **eligible for coverage**.

Small Bowel/Liver Specific
Evidence of intolerance of total parental nutrition includes, but is not limited to, multiple and prolonged hospitalizations to treat total parental nutrition 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 total parental nutrition, thus avoiding the necessity of a multivisceral transplant.

Human immunodeficiency virus positive transplant recipients will be considered **eligible for coverage** when all of the additional criteria are met:

- CD4 count >200 cells/mm-3 for >6 months; and
- HIV-1 RNA undetectable; and
- On stable anti-retroviral therapy >3 months; and
- No other complications from acquired **immune deficiency syndrome** (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioses mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
- All other criteria for transplantation are met.

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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

When patient selection criteria have not been met, small bowel transplant, small bowel/liver transplant and multivisceral transplant are considered **investigational.***

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

Note: 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. Short bowel syndrome is one case of intestinal failure.

Isolated Small Bowel Transplant
Based on review of available data, the Company may consider a small bowel transplant using cadaveric intestine 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 to be **eligible for coverage**.

Based on review of available data, the Company may consider a small bowel transplant using a living donor only when a cadaveric intestine is not available for transplantation in a patient who meets criteria for a cadaveric intestinal transplant to be **eligible for coverage**.

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers the use of a small bowel transplant using living donors in all other situations to be **not medically necessary.****

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on the review of available data, a small bowel transplant for adults and pediatric patients with intestinal failure who are able to tolerate TPN is considered to be **investigational**.*

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Background/Overview

Small bowel/liver transplantation is transplantation 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.

Small bowel transplants are typically performed in patients with short bowel syndrome, defined as an inadequate absorbing surface of the small intestine due to extensive disease or surgical removal of a large portion of small intestine. In some instances, short bowel syndrome is associated with liver failure, often due to the long-term complications of TPN. These patients may be candidates for a small bowel/liver transplant or a multivisceral transplant, which includes the small bowel and liver with 1 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.

Isolated Small Bowel Transplant

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. When the small bowel and liver are transplanted in conjunction with other gastrointestinal organs, the procedure is referred to as a multivisceral transplant. Small bowel/liver transplants and multivisceral transplants are considered in a separate policy.

A small bowel transplant is typically performed in patients 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.

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 1 to 2 years. Prognosis for recovery depends on the degree and location of small intestine damage. Therapy is focused on achieving adequate macro- and micro-nutrient 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. However, some patients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become chronically dependent on 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.

Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2011, 129 intestinal transplants were performed in the United States, of which all but 1 was from deceased donors.

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FDA or Other Governmental Regulatory Approval

Centers for Medicare and Medicaid Services (CMS)
Medicare will cover intestinal transplantation for the purposes of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed TPN and only when performed in centers that meet approved criteria. The criteria for approval of centers will be based on an annual volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65% (these criteria were reviewed again in 2006 and upheld).

Effective for services performed on or after April 1, 2001, this procedure is covered only when performed for patients who have failed TPN and only when performed in centers that meet approval criteria.

1. Failed TPN

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

- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.
- 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, pulmonary embolism, Superior Vena Cava syndrome, or chronic venous insufficiency.
- 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.
- 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.

2. 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.

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Rationale/Source

A 1999 TEC Assessment focused on multivisceral transplantation and offered the following conclusions: Multivisceral transplantation in patients with small bowel syndrome, liver failure, and/or other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract is associated with poor patient and graft survival. Pediatric and adult patients have a similar 2- and 5-year survival of 33% to 50%. However, without this procedure, it is expected that these patients would face 100% mortality.

The published literature consists of case series, mainly reported by single centers. Authors of these reports, as well as reviews, observe that while outcomes continue to improve, recurrent and chronic rejection and complications of immunosuppression continue to be obstacles to long-term survival.

In 2010, Nayyar et al reported that there had been improvements in 5-year actuarial patient and graft survival after liver/small bowel transplant since the use of rabbit antithymocyte globulin induction began to be used in their pediatric center in 2002 (81% vs 58% and 76% vs 52%, respectively). In addition to innovations in immunosuppressive therapy, the authors cited new approaches to management of short gut syndrome including hypoallergenic formulas and modification of enteral nutrition to prevent TPN–induced cholestasis. The authors noted that better understanding of the protective role of the liver in preventing chronic rejection of the small bowel allograft could improve long-term survival after isolated small bowel transplantation.

Other survival data include a 2009 report by Abu-Elmagd et al reporting on their experience with 500 intestinal and multivisceral transplantations. The study found 1- and 5-year patient survival of 92% and 70%, respectively. A 2013 study from a single center in Sweden included 30 patients accepted for intestinal and multivisceral transplantation. One- and 3-year survival rates were 68% and 61%, respectively. Among patients awaiting transplantation after being accepted as candidates, there was a 34% survival rate. In 2013, Mangus et al reported on 95 patients who underwent multivisceral transplantation with or without liver transplantation at 1 site in the U.S. One-year patient survival was 72% and 3-year survival was 57%. The authors noted a learning curve, with a 48% survival rate for transplants performed between 2004 and 2007 and a 70% survival rate for operations between 2008 and 2010.

Several case series have focused on complications after small bowel and multivisceral transplantation. For example, in 2011 Wu et al reported on 241 patients who underwent intestinal transplantation. Of these, 147 (61%) had multivisceral transplants, 65 (27%) had small bowel transplants, and 12% had small bowel/liver transplants. There were 151 children (63%) and 90 adults. A total of 22 patients (9%) developed graft-versus-host disease. Children younger than 5 years-old were more likely to develop this condition; the incidence in this age group was 16 of 121 (13.2%) compared with 2 of 30 (6.7%) in children between 5 and 18 years and 9 of 90 (4.4%) in adults older than 18 years. In addition, a 2012 article retrospectively reported on bloodstream infections among 98 children younger than age 18 years with small bowel/combined organ transplants. Seventy-seven (79%) patients underwent small bowel transplant in combination with a liver, kidney or kidney-pancreas, and 21 had an isolated small bowel transplant. After a median follow-up of 52 months, 58 (59%) patients remained alive. The 1-year survival rate was similar in patients with combined small bowel transplant (75%) and those with isolated small bowel transplant (81%). In the first year after

transplantation, 68 patients (69.4%) experienced at least 1 episode of bloodstream infection. The 1-year survival rate for patients with bloodstream infections was 72% compared with 87% in patients without bloodstream infections (p=0.056 for difference in survival in patients with and without bloodstream infections).

A 2014 single-center Italian case series reported on transplants in 45 patients who received either intestinal transplants alone or a combined transplant procedure. Twelve of the patients had small bowel/multivisceral transplants. Five of these had the procedure due to short-bowel syndrome, 2 had chronic intestinal pseudo-obstruction, and 5 had Gardner syndrome. Survival rates for the entire patient population were 77% at 1 year, 58% at 3 years, 53% at 5 years, and 37% at 10 years.

HIV-Positive Transplant Recipients
This subgroup of recipients has long been controversial, due to the long-term prognosis for human immunodeficiency virus (HIV) positivity and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients primarily consist of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy, which has markedly changed the natural history of the disease. In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant unless the following criteria were present. These criteria may be extrapolated to other organs:

- CD4 count greater than 200 cells/mm-3 for more than 6 months
- HIV-1 RNA undetectable
- On stable antiretroviral therapy for more than 3 months
- No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioses mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
- Meeting all other criteria for transplantation.

In 2006, the British HIV Association and the British Transplantation Society Standards Committee published guidelines for kidney transplantation in patients with HIV disease. As previously described, these criteria may be extrapolated to other organs.

The guidelines, which are similar to those cited here, recommend that any patient with end stage organ disease with a life expectancy of at least 5 years is considered appropriate for transplantation under the following conditions:

- CD4 greater than 200 cells/mL for at least 6 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- Demonstrable adherence and a stable HAART regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after HAART.

Furthermore, as of November 2010, the United Network for Organ Sharing policy on identification of transmissible diseases in organ recipients states, "A potential candidate for organ transplantation whose

test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy."

No studies that reported on outcomes in HIV-positive patients who received small bowel/liver or multivisceral transplants have been identified in literature reviews.

Retransplantation
In 2012, Trevizol et al published a review of literature from the previous 5 years on intestinal and multivisceral retransplantation. The authors found articles from 2 centers. Mazariegos et al reported on 15 retransplantations in 14 pediatric patients. By the end of follow-up, 4 patients had died and 10 patients had a normal graft function. TPN was weaned at a mean of 32 days after retransplantation. A 2009 study by Abu-Elmagd et al, discussed earlier, reported 47 retransplants after 500 intestinal and multivisceral transplantations in adults and children Included were 31 intestinal retransplants, 9 multivisceral retransplants, and 7 intestinal/liver retransplants. For all types of retransplants combined, there is a 5-year survival rate of 47% for all retransplants.

Desai et al reported intestinal retransplantation data from the Organ Procurement and Transplant Network database. Between October 1987 and August 2009, there were 31 cases of small bowel/liver retransplants in adults and 49 in children. Among adults, 1-, 3-, and 5-year survival rates after retransplantation were 63.1%, 56.1%, and 46.8%, respectively. This compares with survival rates after primary small bowel/liver transplants of 67%, 53.3%, and 46% at 1, 3, and 5 years. Among children, there was a 42.1% survival rate at 1, 3, and 5 years after retransplantation. Survival rates after primary small bowel/liver transplantation was 67.6%, 56.1%, and 51.4%, respectively.

Summary
Evidence for small bowel/liver and multivisceral transplant and retransplant consists of case series. Though infrequently performed, the transplant procedures are demonstrated to provide a survival benefit, and the procedure is considered medically necessary for patients who have been managed with long-term total parenteral nutrition and who have developed evidence of impending end-stage liver failure.

Isolated Small Bowel Transplant
The 1995 Assessment concluded that in children, small bowel transplant was associated with improved survival compared with TPN as the associated adverse outcomes for small bowel transplant were offset by severe TPN-related complications. This Assessment also concluded that, in adults, the outcomes for small bowel transplant were worse than that associated with TPN. A 1999 TEC Assessment reevaluated the data on adults and concluded that it is not possible to predict which patients would survive longer on TPN versus small bowel transplant and therefore that transplantation is a reasonable option in selected adults.

This policy has been regularly updated with searches of the MEDLINE database. Much of the published literature consists of case series reported by single centers. These reports, as well as reviews of the reports, observe that while outcomes continue to improve, obstacles to long-term survival remain. Recurrent and chronic rejections and complications of immunosuppression are significant issues in bowel transplantation.

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One issue in the literature is the importance of timely referral for intestinal transplantation to avoid the necessity of combined liver and intestine transplantation. It has been suggested that recent improvements in survival may justify removing the restriction of intestinal transplantation to patients who have severe complications of TPN. However, as noted by Vianna et al in their 2008 report on the status of intestinal transplantation, no randomized trials compare intestinal transplantation with long-term PTN, and optimal timing for earlier transplantation has not been established. This review also noted that the currently reported 1-year graft and patient survival rate for intestinal transplantation was 80%.

Another issue in the literature is the rate of various complications after small bowel transplant. Florescu et al have published several articles retrospectively reviewing complications in a cohort of 98 pediatric patients. Twenty-one of these children (21.4%) had an isolated small bowel transplant; the remainder had combined transplants. A 2012 study reported that 68 of the 98 patients (69%) developed at least 1 episode of bloodstream infection. Among the patients with an isolated small bowel transplant, the median time to infection for those who became infected was 4.5 months (95% confidence interval, 2.4 to 6.7 months). Also in 2012, the researchers reported that 7 of 98 patients (7%) developed cytomegalovirus disease; only 1 of these had an isolated small bowel transplant. In 2010, Florescu et al reported that 25 of 98 cases reviewed (25.5%) developed at least 1 episode of fungal infection; Candida infection was most common. The mortality rate did not differ significantly between patients who did and did not develop a fungal infection (32.3% vs 29.8%, respectively; p=0.46). In 2013, a research group in France reported that 7 of 12 children who had an isolated small bowel transplant had renal function complications at some point after surgery. Before treatment, all of the patients had normal renal functioning.

Living donors
Cadaveric intestines have been most commonly used, but recently there has been interest in using a portion of intestine harvested from a living, related donor. Potential advantages of a living donor include the ability to plan the transplantation electively and better antigen matching, leading to improved management of rejection. Small case reports have been published of 1 or 2 patients with different lengths of the ileum or jejunum. While there appear to be minimal complications to the donors, of the 6 cases reported, 5 recipients remain on TPN for at least part of their nutrition. One patient remains healthy and is off TPN.

Benedetti et al reported outcomes from 4 children and 7 adults who underwent 12 living-related small bowel transplantations between 1998 and 2004. All donors were reported to have had uneventful recovery following removal of up to 40% of the small intestine. The 3-year patient survival was 82%, with graft survival of 75%. Longer follow-up from the earlier cases was not reported. Gangemi and Benedetti published a literature review of living donor small bowel transplantation reports from 2003 to 2006; all of the reports listed Benedetti (et al) as author. The authors comment that, “Due to the excellent result in modern series of deceased donor bowel transplantation, widespread use of the procedure [living donor] should not be recommended, in consideration of the potential risks to donor. Furthermore, few centers have acquired the necessary experience with the procedure.”

In June 2010, Sudan published a review of current literature on long-term outcomes after intestinal transplantation. In this article, the author notes that intestinal transplantation has become standard therapy for patients with life-threatening complications from parenteral nutrition therapy. Data from current single-

center series indicates a 1-year patient survival rate of 78% to 85% and a 5+ year survival rate of 56% to 61%. With respect to pediatric intestinal transplant patients, the majority achieve normal growth velocity at 2 years posttransplant. However, oral aversion is a common problem; tube feedings are necessary in 45% of children. Sudan also reports on parental surveys of quality of life in pediatric transplant patients in which intestinal transplant patients appear to have modestly improved quality of life compared with patients remaining on TPN and slightly worse than matched school-age controls without intestinal disease.

HIV+ transplant recipients
This subgroup of recipients has long been controversial, due to the long-term prognosis for HIV positivity and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients primarily consist of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease.

As of February 2013, the United Network for Organ Sharing (UNOS) policy on HIV-positive transplant candidates states “A potential candidate for organ transplantation whose test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy.” (Policy 4, Identification of Transmissible Diseases in Organ Recipients).

In 2006, the British HIV Association and the British Transplantation Society Standards Committee published guidelines for kidney transplantation in patients with HIV disease. As previously described, these criteria may be extrapolated to other organs.

The guidelines, which are similar to those cited above, recommend that any patient with end-stage organ disease with a life expectancy of at least 5 years is considered appropriate for transplantation under the following conditions:

- CD4 200 cells/micro liter for at least 6 months.
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- Demonstrable adherence and a stable HAART regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after HAART.

Retransplantation
Desai et al have published the most comprehensive reporting of outcomes after repeat small bowel transplant in the United States. A 2012 publication evaluated data in the UNOS database on patients who underwent small bowel transplants in the U.S between October 1987 and August 2009. The investigators identified 41 repeat isolated small bowel transplants in adults and 28 in children. Thirty-nine of the adults (95%) and 27 (96%) of the children had a previous isolated small bowel transplant; the remaining patients had an initial combined small bowel and liver transplant.

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Among adults, survival rates after retransplant were 80% after 1 year, 47% after 3 years and 29% after 5 years. Comparable survival rates for primary isolated small bowel transplant were 84% after 1 year, 67% after 3 years, and 54% after 5 years. Survival was significantly lower after repeat isolated small bowel transplant compared with primary isolated small bowel transplant (p=0.005).

Among children, patient survival was 81% after 1 year, 74% after 3 years, and 58% after 5 years. These rates did not differ significantly from rates after primary isolated small bowel transplant (85% after 1 year, 71% after 3 years, 64% after 5 years, respectively).

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received through 2 physician specialty societies and 2 academic medical centers while this policy was under review for July 2009. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The consensus of those providing input was that small bowel transplant should be performed in patients who are developing severe TPN-related complications and that small bowel transplant from living donors may be considered when cadaveric intestinal transplants are not available.

Summary
Based on the evidence review and clinical input, 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. The available published survival data suggest that small bowel retransplant is a reasonable option after a failed primary small bowel transplant; thus, this may be considered medically necessary. Routine use of living-donor intestinal transplants is considered not medically necessary because the net health outcome associated with this procedure is reduced (compared with cadaveric transplant) because of donor-related morbidity.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	44120, 44121, 44132, 44133, 44135, 44136, 44137, 44715, 44720, 44721, 47133, 47135, 47136, 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147
HCPCS	S2053, S2054, S2055
ICD-9 Diagnosis	570, 572.8, 579.3
ICD-9 Procedure	45.63, 46.97, 50.59

Policy History

Original Effective Date: 01/28/2002
Current Effective Date: 08/20/2014

12/16/2001	Medical Policy Committee review
01/28/2002	Managed Care Advisory Committee approval
06/24/2002	Format Revision. No substance change to policy.
01/20/2004	Medical Policy Committee review. Format Revision Policy revision to include small bowel - transplant alone. No change in coverage eligibility status.
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review

Small Bowel Transplant, Small Bowel/Liver Transplant and Multivisceral Transplant

Policy # 00112
Original Effective Date: 01/28/2002
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01/24/2005	Managed Care Advisory Council approval
02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review. Format Revisions.
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Adequate cardiopulmonary status, absence of infection, no history of malignancy within five years of transplantation, excluding nonmelanomatous skin cancers, and documentation of patient compliance with medical management were added to the patient selection criteria.
04/02/2006	Medical Director review
04/16/2008	Medical Policy Committee approval. "short bowel syndrome" changed to "intestinal failure". Intestinal failure defined. Investigational statement added regarding living donors for small bowel transplants. Coverage eligibility unchanged.
05/07/2009	Medical Director review
05/20/2009	Medical Policy Committee approval. Coverage eligibility unchanged.
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. Contraindications added to policy. "Based on review of available data, the Company considers small bowel transplant using living donors to be investigational* for adults and children" was removed from policy.
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. Statement added that small bowel/liver transplant or multivisceral retransplant may be considered medically necessary after a failed primary small bowel/liver transplant or multivisceral transplant.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Added pediatric patients as investigational for small bowel transplant with intestinal failure who are able to tolerate TPN.

Next Scheduled Review Date: 08/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

Small Bowel Transplant, Small Bowel/Liver Transplant and Multivisceral Transplant

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**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.