



Louisiana

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

Policy # 00112

Original Effective Date: 01/28/2002

Current Effective Date: 11/09/2020

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.*

Small Bowel/Liver and Multivisceral Transplant

Based on review of available data, the Company may consider transplants, such as a multivisceral transplant and a small bowel and liver transplant 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 and who have developed evidence of impending end-stage liver failure to be **eligible for coverage**.**

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

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

- CD4 count >200 cells per cubic millimeter 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, coccidioides 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**.*

A small bowel and liver transplant or multivisceral transplant is considered **investigational*** in all other situations.

Isolated Small Bowel Transplant

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 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**** (See Policy Guidelines section).

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 noted above for a cadaveric intestinal transplant to be **eligible for coverage****.

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

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Louisiana

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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 can tolerate TPN is considered to be **investigational.*** (See Policy Guideline section).

Based on the review of available data, a small bowel transplant is considered **investigational*** in all other situations. (See Policy Guidelines Section).

Policy Guidelines

Small Bowel/Liver and Multivisceral Transplant

General Criteria

Potential contraindications for solid organ transplant that are subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- 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
- Other irreversible end-stage disease not attributed to intestinal failure
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

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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 an example of intestinal failure.

Candidates should meet the following criteria:

- Adequate cardiopulmonary status
- Documentation of patient compliance with medical management.

Small Bowel/Liver-Specific Criteria

Evidence of intolerance of total parenteral nutrition (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 and would thus avoid the necessity of a multivisceral transplant.

Isolated Small Bowel Transplant

General Criteria

Potential contraindications for solid organ transplant subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage diseases not attributed to intestinal failure
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Small Bowel-Specific Criteria

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 1 cause of intestinal failure.

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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 >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.

Background/Overview

Small Bowel/Liver and Multivisceral Transplant

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. 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.

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.

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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. 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. 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.

Isolated Small Bowel Transplant

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. 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 the Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS).

Short Bowel Syndrome

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 the small intestine. The spectrum of clinical disease is widely variable from only single micronutrient malabsorption to complete intestinal failure, defined as the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes. In adults, etiologies of short bowel syndrome include ischemia, trauma, volvulus, and tumors. In children, gastroschisis,

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volvulus, necrotizing enterocolitis, and congenital atresia are predominant causes. Although the actual prevalence of short bowel syndrome is not clear primarily due to under-reporting and a lack of reliable patient databases, its prevalence is estimated to be 30 cases per million in the U.S.

Treatment

The small intestine, particularly the ileum, can 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 focuses 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.

However, some patients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become chronically dependent on TPN. For patients with short bowel syndrome, the rate of parenteral nutrition dependency at 1, 2, and 5 years has been reported to be 74%, 64%, and 48%, respectively. Patients with complications from TPN may be considered candidates for a 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 a recent interest in using living donors.

Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2018, 104 intestinal transplants were performed in the U.S. (59% of which were intestine-liver transplants). Overall, both the number of new patients added to the intestinal transplant waiting list (n=135) and the number of intestinal transplants performed declined to their lowest levels in 2018.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Small Bowel/Liver and Multivisceral Transplant

Small bowel/liver and multivisceral transplantation are surgical procedures and, as such, are not subject to regulation by the U.S. FDA.

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The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

Isolated Small Bowel Transplant

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. FDA.

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

Rationale/Source

Small Bowel/Liver and Multivisceral Transplant

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 limited number of case series. Relevant outcomes are overall survival, 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 case series have revealed fairly high post procedural 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 post transplantation 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.

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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 post transplantation 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.

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. Isolated small bowel transplant is commonly performed in patients with short bowel syndrome.

For individuals who have intestinal failure who receive a small bowel transplant, the evidence includes case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Small bowel transplant is infrequently performed, and only relatively small case series, generally single-center, are available. Risks after small bowel transplant are high, particularly related to infection, but may be balanced against the need to avoid the long-term complications of total parenteral nutrition dependence. In addition, early small bowel transplant may obviate the need for a later combined liver/small bowel transplant. Transplantation is contraindicated in patients in whom the procedure is expected to be futile due to comorbid disease or in whom post transplantation care is expected to worsen comorbid conditions significantly. Guidelines and U.S. federal policy no longer view HIV infection as an absolute contraindication for solid organ transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have failed small bowel transplant without contraindication(s) for retransplant who receive a small bowel retransplant, the evidence includes case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data from a small number of patients undergoing retransplantation are available. Although limited in quantity, the available data have

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suggested a reasonably high survival rate after small bowel retransplantation in patients who continue to meet criteria for transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Based on clinical input, obtained in 2009, small bowel transplantation using a living donor may be considered medically necessary only when a cadaveric intestinal transplant is not available. 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 a cadaveric transplant) due to donor-related morbidity.

Supplemental Information

Small Bowel/Liver and Multivisceral Transplant

Practice Guidelines and Position Statements

American Gastroenterological Association

In 2003, the American Gastroenterological Association published a position statement on short bowel syndrome and intestinal transplantation. The statement noted that only patients with life-threatening complications due to intestinal failure or long-term total parenteral nutrition have undergone intestinal transplantation. The statement recommended the following Medicare-approved indications, pending availability of additional data:

- Impending liver failure
- Thrombosis of major central venous channels
- Frequent central line-associated sepsis
- Frequent severe dehydration.

American Society of Transplantation

In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation. The Society listed the following disorders in children as being potentially treatable by intestinal transplantation: short bowel syndrome, defective intestinal motility, and impaired enterocyte absorptive capacity. Contraindications for intestinal transplant to treat pediatric patients with intestinal failure are similar to those of other solid organ transplants: profound

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neurologic disabilities, life-threatening comorbidities, severe immunologic deficiencies, nonresectable malignancies, autoimmune diseases, and insufficient vascular patency.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare covers intestinal transplantation for the purposes of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed total parenteral nutrition and only when performed in centers that meet approved criteria. The criteria for approval of centers are based on a "volume of 10 intestinal transplants per year with a 1-year actutimes survival rate of 65 percent."

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in June 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

Isolated Small Bowel Transplant

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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.

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2009. 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.

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Practice Guidelines and Position Statements

American Gastroenterological Association

In 2003, the American Gastroenterological Association produced a medical position statement on short bowel syndrome and intestinal transplantation. It recommended dietary, medical, and surgical solutions. Indications for intestinal transplantation mirrored those of the Centers for Medicare & Medicaid Services. The guidelines acknowledged the limitations of transplant for these patients. The statement recommended the following Medicare-approved indications, pending availability of additional data:

- "Impending or overt liver failure...
- Thrombosis of major central venous channels...
- Frequent central line-related sepsis...
- Frequent severe dehydration."

American Society of Transplantation

In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation. The Society listed the following disorders in children as potentially treatable by intestinal transplantation: short bowel syndrome, defective intestinal motility, and impaired enterocyte absorptive capacity. Contraindications for intestinal transplant to treat pediatric patients with intestinal failure are similar to those of other solid organ transplants: profound neurologic disabilities, life-threatening comorbidities, severe immunologic deficiencies, nonresectable malignancies, autoimmune diseases, and insufficient vascular patency.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid have a national coverage determination on intestinal and multivisceral transplantation. The determination covers these types of transplants only when performed for patients who have failed TPN and only when performed in centers that meet approval criteria.

"1. Failed TPN

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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.
- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins.
- Frequent line infection and sepsis.
- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

2. Approved Transplant Facilities

The criteria for approval of centers will be based on a volume of 10 intestinal transplants per year with a 1-year actutimes survival of 65 percent using the Kaplan-Meier technique."

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in June 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

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

Policy # 00112

Original Effective Date: 01/28/2002

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Louisiana

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Louisiana

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Louisiana

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Policy History

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12/16/2001 Medical Policy Committee review

01/28/2002 Managed Care Advisory Committee approval

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Louisiana

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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
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

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- 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.
 - 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
 - 09/03/2015 Medical Policy Committee review
 - 09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 10/06/2016 Medical Policy Committee review
 - 10/19/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
 - 10/05/2017 Medical Policy Committee review
 - 10/18/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 10/04/2018 Medical Policy Committee review
 - 10/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 10/03/2019 Medical Policy Committee review
 - 10/09/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 10/01/2020 Medical Policy Committee review
 - 10/07/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- Next Scheduled Review Date: 10/2021

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 2019 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is

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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, 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147, 47399
HCPCS	S2053, S2054, S2055
ICD-10 Diagnosis	K72.00-K72.01, K72.10-K72.11, K72.90-K72.91, K76.2, K91.2

*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. Food and Drug Administration (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

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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.

****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.

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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.

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