Clinical Medical Policy

Solid Organ and Stem Cell Transplantation – # 081

Last reviewed: 10/14/2026

Application

Application of this Medical Policy applies to:
RIte Care (MED), Rhody Health Partners (RHP), Rhody Health Expansion (RHE), Children with Special Health Care Needs (CSN), Substitute Care (SUB), Commercial (HBE), INTEGRITY for Duals (FIDE), Duals CONNECT (CO-DSNP)
Application Excluded for:
Extended Family Planning (EFP)

Medicare Distinction
For INTEGRITY for Duals (FIDE) and Duals CONNECT (CO-DSNP) members: Neighborhood Health Plan of Rhode Island (Neighborhood) uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations, including medical necessity. Coverage determinations are based on applicable payment policies, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other available CMS published guidance.

In the absence of an applicable or incomplete NCD, LCD, or other Medicare guidelines, then Neighborhood will apply coverage guidance from other widely used treatment guidelines with peer-reviewed scientific evidence, such as InterQual® and/or internal Clinical Medical Policies.

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Description

Transplant evaluations involve a comprehensive medical, psychological, and social assessment to determine whether an individual is an appropriate candidate for transplantation. The transplant team involves a multidisciplinary transplant team, led by a physician, consisting of transplant physicians, transplant surgeons, transplant coordinators, social workers, dietitians, financial coordinators, and pharmacists (if needed). Additional workup with subspecialty physicians may be required depending upon the patient's medical needs and at the discretion of the physician/surgeon. The evaluation helps the transplant team assess whether the procedure can be performed safely and whether the candidate is prepared for the responsibilities associated with transplantation. This process also ensures that the individual understands the potential risks, benefits, and long-term requirements of transplant care, including adherence to treatment before and after the procedure.

Only those plan members accepted for transplant by a Transplant Center and actively listed for transplant will be considered for prior authorization. The member must meet the eligibility criteria for the Transplant Center performing the transplant and be willing and capable of following the post-transplant treatment plan.

A Transplant Program (also referred to as a Transplant Center) is defined as a component within a transplant hospital that provides a particular type of transplantation service.

All solid organ transplants must be performed by a Transplant Center located in a hospital that is:

- A member of the Organ Procurement and Transplantation (OPTN) network. OPTN approved Transplant Centers can be found here.
- For INTEGRITY and CONNECT members, the transplant center must be a CMS (Centers for Medicare and Medicaid Services) approved center for the specific transplant program. CMS approved Transplant Centers can be found here.
- Both CMS and OPTN have requirements that centers must meet, such as transplant volume, graft and patient survival and other pertinent facility statistical data from the Scientific

Registry for Transplant Recipients and the Organ Procurement and Transplantation Network.

All Stem Cell Transplants must be performed by a Transplant Center located in a hospital that is:

- ❖ Accredited by FACT (Foundation for the Accreditation of Cellular Therapy). FACT accredited Transplant Centers can be found here.
- ❖ FACT has a set of requirements to ensure patient safety and outcomes, such as volume of allogeneic stem cell transplants and patient survival reported by Center for International Blood & Marrow Transplant Research (CIBMTR).

Transplant Authorizations

All transplants require prior authorization at the time of:

- ✓ Transplant Evaluation
- ✓ Transplant Listing (for solid organs)
- ✓ Transplant Procedure
- ✓ Post Transplant Follow-up

All in-network and out-of-network providers must submit transplant authorization requests using the **Transplant Prior Authorization Request Form**. Requests may be submitted through one of the following methods:

- ❖ Electronic Submission: E-Form
- ❖ Fax Submission: PDF

To assist providers with completing and submitting transplant requests, Neighborhood has developed a Reference Guide and FAQs for Transplant Requests which provides additional guidance and answers common questions regarding the transplant authorization process.

Approved authorizations for Transplant Services will allow for coverage of tests and services that are standard of care for the transplant being performed.

- ➢ **Any tests and services that are not standard of care for pre-transplant evaluation should be requested separately and must meet their specific medical necessity criteria to be approved.**
- ➢ **Separate authorizations will be required for medications and for services and tests delegated to Evolent.**

Auth Type	Solid Organ(s)	Stem Cell
Transplant Evaluation	• Consultations with the transplant team and other needed specialties (i.e. cardiology, psychiatry, gastroenterology, etc.). • Routine lab tests such as: ○ Blood type and screen, Tissue typing (HLA) ○ CBC/Diff, Platelet, CMP, LFT's ○ Infectious disease screening (CMV IgG/IgM, Hepatitis B & C, HIV, EBV IgG/IgM, RPR, Varicella titers, PPD skin test, etc.) ○ PSA (males > 40 yr.) ○ Panel Reactive Antibodies (PRA) • Additional Tests based on patient characteristics: ○ Colonoscopy ○ Frailty Assessment ○ Height/weight ○ Pap smear and/or Mammogram (females) ○ Ultrasounds, X-Rays ○ Substance and/or alcohol screening ○ Pregnancy ○ Pulmonary function test • Inpatient Authorizations also allow for coverage of the inpatient level of care.	• Everything listed in the Solid Organ(s) Transplant Evaluation section. • Bone marrow aspirations and biopsies • Chimerism testing • Comparative analysis using Short Tandem Repeat (STR) markers
Transplant Listing or Procedure	• Everything listed in the Solid Organ(s) Transplant Evaluation section. • The transplant procedure	• Everything listed in the Stem Cell Transplant Evaluation section. • The transplant procedure
Post Transplant Follow-Up	• Everything listed in the Solid Organ(s) Transplant Evaluation section.	• Everything listed in the Stem Cell Transplant Evaluation section.

Coverage Determination

Neighborhood uses the most recent version of InterQual® criteria to determine the medical necessity of Adult (≥18 years old) and Pediatric (<18 years old) autologous and allogeneic hematopoietic stem cell transplantation and Adult solid organ transplants. Neighborhood makes

InterQual® criteria available to the public through the InterQual® Transparency Tool on our website.

The criteria in this policy are used to evaluate transplant requests in conjunction with InterQual® criteria and, when applicable, in the absence of InterQual® criteria.

Universal Contradictions

The list below outlines the standard contraindications for adult and pediatric solid organ transplantation. Unless otherwise specified, these contraindications apply to all transplant types. Certain transplant procedures may have additional contraindications or specific exceptions. For transplant-specific requirements and limitations, please refer to the Contraindications section for the applicable organ(s) within this policy.

- Infections: Systemic or uncontrolled infection including sepsis
- Significant uncorrectable life-limiting medical conditions
- Severe end-stage organ damage that would have an impact on patient survival.
- Active untreated or untreatable malignancy
- Irreversible, severe brain damage
- Active substance use disorders: Although there is no evidence-based consensus regarding an optimal duration of sobriety prior to transplantation, a period of abstinence appropriate to the member's clinical condition is generally expected. This period may allow for sufficient clinical improvement and, in some cases, eliminate the need for transplantation. Refer to the organ-specific transplant sections below for additional guidance and requirements.
- Insufficient patient and/or caregiver understanding of the post procedure adherence and follow-up.
- Inadequate social or family support
- Inactive alcohol and/or substance abuse (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication.
- Recreational or medicinal use of marijuana is not a contraindication.

Universal Special Considerations

The following are consistent with widely accepted clinical practice guidelines.

Solid Organ and Stem Cell Transplants:

- Members with a history of malignancy require an oncology evaluation to determine status of disease.
- Social and psychiatric issues can have a significant impact on the outcomes of a transplant. It is expected that a psychosocial evaluation and/or psychiatry consultation is obtained as part of the standard transplant evaluation (Crone et al., 2010). The evaluation should address the following:
    - Overall functioning

- Understanding of underlying illness and need for proposed treatment
- History of adherence and compliance and barriers to compliance
- Quality of relationships
- Presence of a supportive caregiver
- Social history, including educational level and employment history.
- Housing and living situation, including reliable transportation to attend medical visits.
- Socioeconomic status, including sufficient funding to pay for immunosuppressive medications post-transplant.
- Current and past history of alcohol and substance use and abuse
- Current and past psychiatric history, including baseline cognitive status and coping skills.

❖ Members with human immunodeficiency virus (HIV) infection must be on a highly active antiretroviral therapy (HAART) regimen and there must be documented evidence of sustained viral load suppression.

Solid Organ Specific:

❖ Gastrointestinal (GI) clearance may be indicated in patients with a history of complicated or active GI disorders.

❖ Pediatric members should have a normal history and physical, or if there is any indication of abnormal cardiac function, cardiology evaluation should be obtained.

Stem Cell Transplant Specific:

❖ Members with HIV should have a formal infectious disease consult indicating adequate treatment and proper assessment of risks related to this transplant.

❖ Serum creatinine > 2.5 mg/dL (≥ 1.5 mg/dL in children) or GFR < 50ml/min.

❖ Serum creatinine may be higher in patients with multiple myeloma or other plasma cell dyscrasias. Members with multiple myeloma with reduced renal function are not prohibited from undergoing autologous SCT when the decreased renal function is related to the multiple myeloma (myeloma kidney). This includes members on hemodialysis with no other contraindications.

❖ Active untreated or untreatable malignancy in members undergoing stem cell transplantation for non-malignant indications.

❖ Members with post-transplant lymphoproliferative disease (PTLD), having failed other conventional therapies, must have no active disease as demonstrated by negative positron emission tomography (PET) scan and resolved adenopathy on computed tomography (CT) and/or magnetic resonance imaging (MRI).

Considerations for Substance Use Disorder

For members experiencing catastrophic clinical decompensation where a period of abstinence is not feasible due to the severity of their medical condition, consideration for transplantation may proceed

only if the transplant center has an established institutional protocol that includes, at a minimum, the following:

- A comprehensive psychosocial evaluation and proactive intervention plan designed to support post-transplant success.
  - Presence of close supportive social network
  - Absence of severe coexisting behavioral health disorders that would negatively impact a treatment plan.
  - Documentation of insight on the member's part of the genesis of this condition and how substance use contributed to the process.
  - There must be documentation of a plan for post-transplantation rehabilitation and monitoring.
  - The member must agree to participate in such a program and commit to lifelong abstinence from addictive substances.
- Evaluation by a dedicated psychiatrist, psychologist, or an appropriate addiction specialist indicating high likelihood of success of post-transplant rehabilitation and abstinence.
- Approval by a transplant selection committee that includes, in addition to the regular members, a dedicated psychiatrist, psychologist, or an appropriate addiction specialist.
- Any other substance abuse needs to be addressed.
- Inactive alcohol and/or substance abuse (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication.

Criteria

Transplant Procedures for INTEGRITY and CONNECT Members

Transplant services for INTEGRITY and CONNECT members are reviewed using CMS NCDs and LCDs when available. Applicable NCDs and LCDs are below:

Transplant Type	NCD	LCD/LCA
Stem Cell	110.23 Stem Cell Transplantation	L39513/A59311
Liver	260.1 Adult Liver Transplantation 260.2 Pediatric Liver Transplantation	
Heart	260.9 Heart Transplants	
Intestinal and Multi-Visceral	260.5 Intestinal and Multi-Visceral Transplantation	
Islet Cell	260.3.1 Islet Cell Transplantation in the Context of a Clinical Trial	
Pancreas	260.3 Pancreas Transplants	

Autologous and Allogeneic Stem Cell Transplants

Hematopoietic stem cell transplantation (HSCT), including peripheral blood stem cell, bone marrow, and cord blood transplantation, is commonly used to treat hematologic malignancies and disorders of the immune system. There are two primary types of HSCT: autologous and allogeneic. In an autologous transplant, the patient's own stem cells are collected and reinfused following treatment. This approach is most frequently used for conditions such as lymphoma, multiple myeloma, and select solid tumors, including testicular cancer and neuroblastoma, as well as certain pediatric malignancies.

In an allogeneic transplant, stem cells are obtained from another individual, who may be a related or unrelated donor and may be either fully matched or partially matched. Allogeneic transplantation is most commonly used to treat leukemias, lymphomas, and inherited nonmalignant disorders. A key advantage of allogeneic transplantation is the graft-versus-tumor effect, in which donor immune cells help eliminate residual malignant cells. However, this benefit must be balanced against the risk of graft-versus-host disease (GVHD), making allogeneic transplantation a more complex treatment option requiring careful donor selection and post-transplant management.

Neighborhood considers Autologous and Allogeneic Stem Cell Transplantation medically necessary when none of the Universal Contraindications are present and the indicated criteria are met. For initial and repeat transplantation, Neighborhood applies the following criteria:

Type of Transplant	Pediatric InterQual® Subset	Adult InterQual® Subset
Allogeneic Stem Cell	CP: Procedures - Transplantation, Allogeneic Stem Cell (Pediatric)	CP: Procedures - Transplantation, Allogeneic Stem Cell
Autologous Stem Cell	CP: Procedures - Transplantation, Autologous Stem Cell (Pediatric)	CP: Procedures - Transplantation, Autologous Stem Cell

Renal (Kidney) Transplantation

Kidney transplantation is a well-established treatment for end-stage renal disease (ESRD) and involves the surgical implantation of a healthy kidney from a deceased donor, living related donor, or living unrelated donor into a recipient with irreversible kidney failure. ESRD, also known as stage 5 chronic kidney disease, occurs when the kidneys can no longer adequately filter waste products and excess fluid from the blood. It is generally defined by a glomerular filtration rate (GFR) of less than 15 mL/min/1.73 m^2 and is considered life-threatening without renal replacement therapy.

Dialysis serves as an artificial means of replacing certain kidney functions and may be used as long-term therapy for individuals who are not candidates for transplantation or who elect not to undergo transplant. It may also be used as a temporary measure while awaiting kidney transplantation.

Kidney transplantation using organs from deceased or living donors remains the preferred treatment for many individuals with ESRD, offering improved survival and quality of life compared with long-term dialysis.

Neighborhood considers Renal Transplantation medically necessary when none of the Universal or Transplant Specific Contraindications are present and the indicated criteria are met.

	Type	Criteria
ADULTS	**Initial**	• InterQual® CP: Procedures – Transplantation, Renal
	Repeat	• Member has a failed primary transplant, **and** • Meets initial InterQual® criteria for transplantation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The Transplant Center recommends repeat transplantation.
PEDIATRIC	**Initial**	• Reviewed on a case-by-case basis after member has undergone a full evaluation, **and** • The pediatric renal transplant team recommends transplantation.
	Repeat	• Member has a failed primary transplant, **and** • Has undergone a full evaluation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The pediatric renal transplant team recommends repeat transplantation.

Transplant Specific Contraindications: Please review the Universal Contraindications found at the beginning of the policy. These apply to all transplants unless otherwise noted below. Additional contraindications that are specific to this specific type of transplant are noted below.

- ❖ Reversible renal failure.

Cardiac (Heart) Transplantation

Heart transplantation involves replacing a diseased or failing heart with a healthy donor heart. It is an established treatment for individuals with refractory end-stage heart disease who continue to experience severe symptoms and functional impairment despite optimal medical and surgical management.

Heart transplantation remains the treatment of choice for carefully selected patients with advanced heart failure and significantly reduced functional capacity when other therapies are no longer effective. Heart failure occurs when the heart is unable to pump sufficient blood to meet the body's metabolic demands and may result from a variety of underlying conditions, including ischemic heart disease, cardiomyopathy, valvular heart disease, or congenital heart defects.

For eligible patients with end-stage heart failure, heart transplantation can provide substantial improvements in survival, functional status, and quality of life.

Neighborhood considers Cardiac Transplantation medically necessary when none of the Universal or Transplant Specific Contraindications are present and the indicated criteria are met.

	Type	Criteria
ADULTS	**Initial**	• InterQual® CP: Procedures – Transplantation, Cardiac
	Repeat	• Member has a failed primary transplant, **and** • Meets initial InterQual® criteria for transplantation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The Transplant Center recommends repeat transplantation.
PEDIATRIC	**Initial**	• Covered for Congenital heart disease (CHD) that is not amenable to surgical therapy or that has failed previous surgical correction (Patel, 2009). • Reviewed on a case-by-case basis after member has undergone a full evaluation, **and** • The pediatric cardiac transplant team recommends transplantation.
	Repeat	• Member has a failed primary transplant, **and** • Has undergone a full evaluation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The pediatric cardiac transplant team recommends repeat transplantation.

Transplant Specific Contraindications: Please review the Universal Contraindications found at the beginning of the policy. These apply to all transplants unless otherwise noted below. Additional contraindications that are specific to this specific type of transplant are noted below.

Unless otherwise specified, these recommendations are consistent with the 2024 International Society for Heart and Lung Transplantation Guidelines for the Evaluation and Care of Cardiac Transplant Candidates (Peled et al., 2024).

- ❖ Significant peripheral vascular disease not correctable with surgery.
- ❖ Significant uncorrectable life-limiting medical conditions such as severe end-stage organ damage including severe diabetes mellitus with end organ damage, irreversible severe pulmonary disease, with FEV1 < 1 L or FVC < 50%, irreversible severe hepatic disease, irreversible severe renal disease, etc. (Acker & Jessup, 2011).
- ❖ Active systemic and/or uncontrolled infection associated with left ventricular assist device.
- ❖ Ongoing tobacco use. It is reasonable to consider active tobacco smoking as a relative contraindication to transplantation. Active tobacco smoking during the previous 6 months is a risk factor for poor outcomes after transplant (Peled et al., 2024).

Heart-Kidney Transplantation

Heart-kidney transplantation is a complex surgical procedure that involves the simultaneous transplantation of a heart and kidney from a deceased donor. This combined transplant approach may be considered for individuals with advanced, irreversible heart and kidney disease who meet established criteria for both heart and kidney transplantation and whose conditions have not responded adequately to medical and/or surgical treatment.

Combined heart-kidney transplantation is typically reserved for carefully selected candidates with end-stage heart failure and significant renal dysfunction that is unlikely to improve following heart transplantation alone. For these individuals, transplantation of both organs may offer improved survival, enhanced quality of life, and reduced risk of persistent kidney failure after transplant.

Neighborhood considers Heart-Kidney Transplantation medically necessary for adult and pediatric members when none of the Universal or Transplant Specific Contraindications for the specific organs are present **and** the transplant-specific criteria below is met.

Member has **at least one** of the following:

- Heart transplant candidates with an established GFR < 30ml/min/1.73 m2 or who are on dialysis may be considered for simultaneous heart kidney transplant.
- If there is evidence of CKD and/or AKI not reversible despite optimizing cardiac function, the member would be considered to have established kidney disease and may be a candidate for simultaneous heart/kidney transplant.
- Candidates for simultaneous heart/kidney transplantation must undergo evaluation by both organ transplantation teams.

Heart-Kidney Repeat Transplantation: Repeat transplantation may be medically necessary when:

1. Member has a failed primary transplant, **and**
2. Meets initial criteria for transplantation (see above), **and**
3. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and**
4. The Transplant Center recommends repeat transplantation.

Heart-Liver Transplantation

Combined heart-liver transplantation (CHLT) is a rare, lifesaving surgical procedure that involves the simultaneous transplantation of both the heart and liver during a single operation. It is typically reserved for carefully selected individuals with end-stage heart failure and irreversible liver disease who meet established criteria for transplantation of both organs. By addressing failure of both organ

systems concurrently, CHLT may improve survival and quality of life in patients for whom isolated heart or liver transplantation would not provide an adequate long-term outcome.

Historically, the most common indications for heart-liver transplantation have included congenital heart disease, metabolic and genetic disorders that affect the heart and liver, combined end-stage heart and liver failure, and restrictive cardiomyopathy. CHLT requires multidisciplinary evaluation and careful candidate selection due to the complexity of the procedure and the need to optimize outcomes for both transplanted organs. For appropriately selected patients, combined transplantation can provide a durable treatment option that addresses the underlying causes of simultaneous cardiac and hepatic failure.

Neighborhood considers Heart-Liver Transplantation medically necessary for adult and pediatric members when none of the Universal or Transplant Specific Contraindications for the specific organs are present **and** the transplant-specific criteria below is met.

Member has **at least one** of the following:

- Primary heart disease with secondary cardiac cirrhosis caused by chronic hepatic venous outflow obstruction including:
  - Members with CHD that required Fontan procedure who ultimately experienced progressive hepatic fibrosis.
  - Hereditary transthyretin (ATTR) amyloidosis leading to cardiomyopathy.
- Primary indication for liver transplant with concurrent heart disease such as:
  - Arrhythmogenic right ventricular cardiomyopathy
  - Hypertrophic cardiomyopathy
  - Dilated nonischemic and ischemic cardiomyopathy
  - Congenital constrictive and radiation-induced cardiomyopathy
  - Sarcoidosis

Heart-Liver Repeat Transplantation: Repeat transplantation may be medically necessary when:

1. Member has a failed primary transplant, **and**
2. Meets initial criteria for transplantation (see above), **and**
3. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and**
4. The Transplant Center recommends repeat transplantation.

Heart-Lung Transplantation

Heart-lung transplantation is a complex surgical procedure that involves the simultaneous transplantation of the heart and one or both lungs from a single deceased donor. Heart-lung transplantation is generally reserved for individuals with end-stage cardiopulmonary disease when isolated heart or lung transplantation is not expected to provide an adequate outcome.

Historically, the most common indications for heart-lung transplantation have included Eisenmenger syndrome, idiopathic pulmonary arterial hypertension, and cystic fibrosis. Eisenmenger syndrome is a complication of certain congenital heart defects in which a longstanding left-to-right cardiac shunt leads to progressive pulmonary vascular disease and elevated pulmonary vascular resistance. As pulmonary pressures rise, blood flow through the shunt may reverse, resulting in systemic hypoxemia and cyanosis. In carefully selected patients with advanced cardiopulmonary disease, heart-lung transplantation may provide a life-saving treatment option when no other effective therapies are available.

Neighborhood considers Heart-Lung Transplantation medically necessary for adult and pediatric members when none of the Universal or Transplant Specific Contraindications for the specific organs are present **and** the transplant-specific criteria below is met.

1. Member has end-stage pulmonary vascular disease with end-stage non-reversible cardiac disease secondary to one of the following:
    a. Primary pulmonary hypertension
    b. Eisenmenger syndrome with a cardiac defect not correctable by surgical repair
    c. Members who are appropriate for single or double lung transplantation and who have severe cardiac disease not otherwise treatable.

Heart-Lung Repeat Transplantation: Repeat transplantation may be medically necessary when:

1. Member has a failed primary transplant, **and**
2. Meets initial criteria for transplantation (see above), **and**
3. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and**
4. The Transplant Center recommends repeat transplantation.

Lung Transplantation

Lung transplantation is a surgical procedure in which one or both diseased lungs are replaced with healthy donor lungs. Common indications for lung transplantation include, but are not limited to, interstitial lung diseases (including idiopathic pulmonary fibrosis), chronic obstructive pulmonary disease (COPD), cystic fibrosis, alpha-1 antitrypsin deficiency, pulmonary arterial hypertension, lymphangioleiomyomatosis (LAM), sarcoidosis, Eisenmenger syndrome, and severe bronchiectasis. Although transplantation may be considered in carefully selected older adults, recipients over 70 years of age generally experience lower long-term survival rates and a higher risk of adverse outcomes compared with younger transplant recipients.

Neighborhood considers Lung (single or double) Transplantation medically necessary when none of the Universal or Transplant Specific Contraindications are present and the indicated criteria are met.

	Type	Criteria
ADULTS	**Initial**	• InterQual® CP: Procedures – Transplantation, Lung
	Repeat	• Member has a failed primary transplant, **and** • Meets initial InterQual® criteria for transplantation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The Transplant Center recommends repeat transplantation.
PEDIATRIC	**Initial**	• Reviewed on a case-by-case basis after member has undergone a full evaluation, **and** • The pediatric lung transplant team recommends transplantation.
	Repeat	• Member has a failed primary transplant, **and** • Has undergone a full evaluation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The pediatric lung transplant team recommends repeat transplantation.

Special Considerations:
Neighborhood will consider the following types of transplants for the circumstances and/or diagnoses listed below:

- **Bilateral Lung Transplantation:**
  - Generalized bronchiectasis.
  - Cystic fibrosis disease
  - Severe pulmonary hypertension with pulmonary arterial pressure > 40 mmHg

- **Living Lobar Lung Transplant:**
  - May be medically necessary in children or small adults with small chest size if size matching is acceptable.
  - May be medically necessary in cases where it is clear a Member will not live long enough to receive a cadaveric transplant.

Transplant Specific Contraindications: Please review the Universal Contraindications found at the beginning of the policy. These apply to all transplants unless otherwise noted below. Additional contraindications that are specific to this specific type of transplant are noted below.

Unless otherwise specified, these recommendations are consistent with the International Society for Heart and Lung Transplantation (ISHLT) Consensus Document for the Selection of Lung Transplant Candidates (Leard et al., 2021)

- Significant chest wall/spinal deformity (Moreno, 2008)

- ❖ Active substance use or dependence that is deemed by the treating team to negatively impact the member and/or the transplanted organ, including current tobacco use, vaping, marijuana smoking, or IV drug use.
- ❖ Glomerular filtration rate < 40 mL/min/1.73m2 unless being considered for multi-organ transplant.
- ❖ Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia)
- ❖ Stroke within 30 days.
- ❖ Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multiorgan transplant.
- ❖ Acute liver failure
- ❖ Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery
- ❖ Ongoing tobacco use. It is reasonable to consider active tobacco smoking as a relative contraindication to transplantation. Active tobacco smoking during the previous 6 months is a risk factor for poor outcomes after transplant (Peled et al., 2024).

Liver Transplantation

Liver transplantation, also known as hepatic transplantation, involves replacing a diseased liver with a healthy whole or partial liver obtained from either a living or deceased donor. Indications for liver transplantation include end-stage liver disease, acute liver failure, and select benign or malignant liver tumors. Candidate priority for transplantation is determined using mortality risk and disease severity criteria established by the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS). Disease severity is assessed using the Model for End-Stage Liver Disease (MELD) score for adults and the Pediatric End-Stage Liver Disease (PELD) score for pediatric patients.

Neighborhood considers Liver Transplantation medically necessary when none of the Universal or Transplant Specific Contraindications are present and the indicated criteria are met.

	Type	Criteria
ADULTS	**Initial**	• InterQual® CP: Procedures – Transplantation, Liver
	Repeat	• Member has a failed primary transplant, **and** • Meets initial InterQual® criteria for transplantation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The Transplant Center recommends repeat transplantation.

PEDIATRIC	**Initial**	• Reviewed on a case-by-case basis after member has undergone a full evaluation, **and** • The pediatric liver transplant team recommends transplantation.
	Repeat	• Member has a failed primary transplant, **and** • Has undergone a full evaluation, **and** • No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and** • The pediatric liver transplant team recommends repeat transplantation.

Transplant Specific Contraindications:
Please review the Universal Contraindications found at the beginning of the policy. These apply to all transplants unless otherwise noted below. Additional contraindications that are specific to this specific type of transplant are noted below.

Unless otherwise specified, these recommendations are consistent with the 2013 American Association for the Study of Liver Disease (AASLD) Clinical Practice Guidelines (Martin et al., 2014):

- Active untreated or untreatable non-hepatic malignancy
- Hepatocellular carcinoma that exceeds University of California, San Francisco (UCSF) criteria, including any of the following:
  - A single lesion measuring greater than 6.5 cm
  - 2–3 lesions with:
    - At least one lesion measuring greater than 4.5 cm; OR
    - Total combined tumor diameter measuring greater than 8 cm
  - Presence of extra-hepatic disease
  - Evidence of major vessel involvement
- Congenital abnormalities that will preclude a liver transplant

Liver-Kidney Transplantation

Combined liver-kidney transplantation (CLKT), also referred to as simultaneous liver-kidney transplantation (SLK), is a surgical procedure in which both the liver and kidney are transplanted during the same operation using organs from a deceased donor. This procedure is indicated for individuals with irreversible failure of both organs and provides a treatment option for patients who meet medical criteria for both liver and kidney transplantation.

CLKT is most commonly performed in adults with advanced liver disease accompanied by chronic kidney disease or kidney failure. In pediatric patients, indications are less common and are often related to congenital or inherited disorders, including liver-based metabolic diseases that result in kidney dysfunction, as well as conditions that affect both the liver and kidneys. By addressing failure

of both organs simultaneously, CLKT can improve outcomes and eliminate the need for separate transplant procedures.

Neighborhood considers CLKT medically necessary for adult and pediatric members when none of the Universal or Transplant Specific Contraindications for the specific organs are present **and** the transplant-specific criteria below is met.

1. Member meets criteria for liver transplantation; **AND**
2. Member has **at least one** of the following:
    a. Sustained acute kidney injury (AKI) as evidence by:
        i. Dialysis at least once every 7 days for the last 6 weeks
        AND/OR
        ii. eGFR ≤ 25 mL/min at least once every 7 days for the last 6 weeks
    b. Chronic kidney disease (CKD) as defined by the National Kidney Foundation (see definition below) **AND** at least one of the following:
        i. Regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.
        ii. eGFR ≤ 30 mL/min at time of listing
    c. Diagnosed with at least one of the following metabolic diseases:
        i. Hyperoxaluria
        ii. Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I
        iii. Familial non-neuropathic systemic amyloidosis
        iv. Methylmalonic aciduria

NOTE: The National Kidney Foundation defines CKD as:

1. GFR < 60 ml/min/1.73 m2 for ≥ 3 months, with or without kidney damage.
2. Kidney damage for ≥ 3 months, as defined by structural or functional abnormalities of the kidney, with or without decreased GFR, manifest by either:
    a. Pathological abnormalities; or
    b. Markers of kidney damage, including abnormalities in the composition of the blood or urine, or abnormalities in imaging tests

CLKT Repeat Transplantation: Repeat transplantation may be medically necessary when:

1. Member has a failed primary transplant, **and**
2. Meets initial criteria for transplantation (see above), **and**
3. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and**
4. The Transplant Center recommends repeat transplantation.

Intestinal and Mult visceral Transplantation

Small bowel transplantation (SBT), small bowel-liver transplantation (SBLT), and multivisceral transplantation (MVT) are surgical procedures performed to treat patients with irreversible intestinal failure and/or multiorgan abdominal failure who can no longer be adequately sustained with total parenteral nutrition (TPN). The primary goals of transplantation are to restore gastrointestinal function, improve nutrient absorption, and eliminate or reduce dependence on long-term TPN.

The types of intestinal transplantation include:

- **Small Bowel Transplantation (SBT):** Transplantation of part or all of the small intestine for individuals with irreversible intestinal failure.
- **Small Bowel-Liver Transplantation (SBLT):** Transplantation of the small intestine and liver for individuals with intestinal failure who have developed irreversible or impending end-stage liver disease, often as a complication of long-term TPN.
- **Multivisceral Transplantation (MVT):** Transplantation of the small intestine along with multiple abdominal organs, indicated for patients with irreversible failure of three or more abdominal organs.

Intestinal failure is characterized by the loss of absorptive capacity and the inability to maintain adequate protein-energy, fluid, electrolyte, or micronutrient balance. Intestinal transplantation may be considered for pediatric and adult members with irreversible intestinal failure who require long-term TPN and have developed serious TPN-related complications, including recurrent or prolonged hospitalizations, loss of central venous access, or progressive liver dysfunction. In members with progressive liver disease resulting from chronic TPN, timely small bowel transplantation may prevent progression to end-stage liver failure and potentially avoid the need for multivisceral transplantation. When intestinal failure is accompanied by irreversible or impending end-stage liver disease, combined small bowel-liver transplantation may be appropriate.

Most intestinal transplants utilize organs from deceased donors. Living donor intestinal transplantation has been performed in a limited number of cases and may offer advantages such as reduced waiting times, improved donor-recipient compatibility, planned elective surgery, and reduced cold ischemia time. However, its use remains uncommon due to the potential risks to the living donor.

Neighborhood considers Intestinal and Multivisceral Transplantation medically necessary for adult and pediatric members when none of the Universal or Transplant Specific Contraindications are present **and** the transplant-specific criteria below is met.

Small Bowel Transplantation (SBT):

1. Diagnosis of irreversible intestinal failure OR severe short bowel syndrome (gastrostomy, duodenostomy, and/or residual small bowel <10 cm in infants and <20 cm in adults) OR abdominal malignancy; **AND**

2. Life-threatening complications attributable to intestinal failure and/or long-term TPN therapy that include ANY of the following:
    a. Impending or overt liver dysfunction (increased serum bilirubin and/or liver enzyme levels, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding, hepatic fibrosis or cirrhosis).
    b. Thrombosis of two or more major central venous channels (e.g., subclavian, jugular, or femoral veins) causing difficult venous access for TPN administration or occlusion of a brachiocephalic vein in children.
    c. Repeated central line-related sepsis (defined as two episodes of systemic sepsis secondary to line infection per year, or one episode of line-related fungemia, septic shock, and/or acute respiratory distress syndrome).
    d. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.
    e. Multiple and prolonged hospitalizations to treat TPN-related complications.

Small Bowel-Liver Transplantation (SBLT)

1. All criteria above for Small Bowel Transplantation (SBT) is met; **AND**
2. Member has developed impending end-stage liver failure as evidenced by ANY of the following conditions:
    a. Elevated serum bilirubin and/or liver enzymes
    b. Splenomegaly
    c. Thrombocytopenia
    d. Gastroesophageal varices
    e. Coagulopathy
    f. Stomal bleeding
    g. Hepatic fibrosis/cirrhosis

Multivisceral Transplantation (MVT):

Common indications for multivisceral transplantation (includes small bowel and liver; and at least one other organ such as the stomach, duodenum, jejunum, ileum, pancreas, or colon) for adults include short bowel syndrome, mesenteric ischemia (arterial or venous), abdominal neoplasms, inflammatory bowel disease, radiation enteritis, and trauma. Common indications for children include volvulus, gastroschisis, necrotizing enterocolitis, congenital intestinal dysmotility diseases (ex aganglionosis, Hirschsprung's disease), and intestinal atresias.

1. All criteria above for Small Bowel-Liver Transplantation (SBLT) is met; **AND**
2. Require 1 or more abdominal visceral organs to be transplanted due to concomitant organ failure or anatomical abnormalities that preclude a small bowel/liver transplant, in addition to ANY of the following:

a. Thromboses of the celiac axis, and the superior mesenteric artery; OR
b. Pseudo-obstruction, localized tumors or other causes of vascular occlusion affecting the arterial blood supply to stomach, liver, small bowel, and pancreas; OR
c. Massive gastrointestinal polyposis; OR
d. Generalized hollow visceral myopathy or neuropathy; OR
e. Pancreatic failure.

SBT, SBLT, MVT Repeat Transplantation: Repeat transplantation may be medically necessary when:

1. Member has a failed primary transplant, **and**
2. Meets initial criteria for transplantation (see above), **and**
3. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and**
4. The Transplant Center recommends repeat transplantation.

Pancreas And Kidney-Pancreas Transplantation

Pancreas transplantation is a treatment option for members with Type 1 diabetes mellitus and, in select cases, brittle diabetes with significant metabolic instability. The primary objective of the procedure is to achieve improved glycemic control and enhance quality of life. Successful pancreas transplantation can eliminate the need for exogenous insulin, reduce or eliminate the need for renal dialysis, and prevent or delay complications related to diabetes, including diabetic nephropathy, retinopathy, neuropathy, vasculopathy, and macrovascular disease.

There are 3 variations of pancreas and kidney/pancreas transplants:

1. **Simultaneous Pancreas-Kidney Transplantation (SPK):** Both organs can be inserted during one procedure.
2. **Pancreas After Kidney (PAK):** The pancreas can be transplanted after a kidney transplant.
3. **Pancreas Transplant Alone (PTA):** The pancreas can be transplanted alone.

Neighborhood considers SPK, PAK, and PTA Transplantation medically necessary for adult and pediatric members when none of the Universal or Transplant Specific Contraindications are present **and** the transplant-specific criteria below are met.

Pancreas Transplant Alone (PTA)

1. The member has undergone at least 12 months of appropriate, comprehensive management under the supervision of an endocrinologist or pancreas transplant surgeon; **AND**
2. Documentation of **one** of the following:
    a. Insulin dependent Type 1 diabetes showing abnormal beta cell functioning as evidenced by ONE of the following:
        i. Beta cell autoantibody positive

ii. Fasting C-peptide undetectable (e.g., < 110% of the laboratory's lower limit of normal and with a concurrently obtained fasting glucose < 225mg/dl)

b. Documented history of frequent, medically uncontrolled, labile (brittle) insulin dependent diabetes mellitus, with recurrent, acute, and severe life-threatening metabolic complications that have required previous hospitalization (e.g., ketoacidosis, hypoglycemia, or hyperglycemia attacks)

AND

3. Consistent failure of aggressive insulin management (e.g., insulin pump, adjusting amounts and frequencies of injected insulin, multiple daily blood glucose levels, and strict diet and exercise); **AND**
4. Creatinine clearance glomerular filtration rate of > 80ml/min; **AND**
5. No significant proteinuria; **AND**
6. Appropriate candidates will have all of the following characteristics:
   a. Insulin requiring diabetes for > 5 years receiving ≤ 1 unit/kg/day
   b. BMI < 30
   c. Age < 60
   d. No history of major vascular events such as bilateral limb amputations and disabling CVA
   e. Not actively smoking
   f. Left ventricular ejection fraction ≥ 40% with no left ventricular hypertrophy

Simultaneous Pancreas-Kidney Transplantation (SPK)

1. All criteria for kidney transplant are met; **AND**
2. The member has insulin-dependent diabetes.

NOTE: The criteria for coverage of a pancreas transplant alone are not applicable when a kidney is also being transplanted.

Pancreas After Kidney (PAK)

1. The member has insulin-dependent diabetes.
2. The Member has a living organ donor for the kidney transplant procedure otherwise SPK should be considered.
3. Previously successful kidney transplant as evidenced by stable function of previous renal allograft.
4. Stable adequate kidney function as evidenced by creatinine clearance glomerular filtration rate of > 45ml/min.
5. No significant proteinuria.

NOTE: The criteria for coverage of a pancreas transplant alone are not applicable when the member has already had a kidney transplant.

PTA, SPK, and PAK Repeat Transplantation: Repeat transplantation may be medically necessary when:

1. Member has a failed primary transplant, **and**
2. Meets initial criteria for transplantation (see above), **and**
3. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant, **and**
4. The Transplant Center recommends repeat transplantation.

Autologous Pancreas Islet Cell Transplantation is covered as an adjunct to pancreatectomy done for chronic pancreatitis.

Allogeneic (living/cadaver donor) Islet Cell Transplantation is considered investigational for members with Type I Diabetes Mellitus and all other situations.

Transplant Specific Contraindications: Please review the Universal Contraindications found at the beginning of the policy. These apply to all transplants unless otherwise noted below. Additional contraindications that are specific to this specific type of transplant are noted below.

- Significant cardiac disease:
  - Non-correctable coronary artery disease
  - Ejection fraction (LVEF, EF) < 40%

Multi-Organ Transplantation

For multi-organ transplants not specifically addressed in this policy, the member must meet criteria for each organ being transplanted.

Limitations and Exclusions

Additional organ or disease-specific contraindications may be found in the organ or transplant-specific section of this policy.

1. Transplant services are not covered if any of the following apply to the member receiving the transplant:

a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery.
b. Chronic illness, aside from which the transplant is indicated, with one year or less life expectancy.
c. Malignant neoplasm, aside from which the transplant is indicated and excluding localized skin cancer, with a high risk for reoccurrence, non-curable malignancy.
d. Systemic and/or uncontrolled infection.
e. Severe end-stage organ damage that would have an impact on patient survival.
f. Irreversible, severe brain damage.
g. AIDS (CD4 count < 200 cells/mm-3).
h. Significant uncorrectable life-limiting medical conditions.
i. Unwilling or unable to follow post-transplant regimen as documented by history of non-compliance and/or inability to adhere to follow through with medication adherence or office follow up.
j. Severe, non-reversible functional or cognitive impairment that prevents the Member from tolerating transplant surgery or participating in essential post-transplant rehabilitation.
k. Insufficient patient and/or caregiver understanding of the post procedure adherence and follow-up.
l. Inadequate social or family support
m. Active pregnancy
n. Active alcohol and/or substance use disorders: Although there is no evidence-based consensus regarding an optimal duration of sobriety prior to transplantation, a period of abstinence appropriate to the member's clinical condition is generally expected. This period may allow for sufficient clinical improvement and, in some cases, eliminate the need for transplantation.

2. Any of the following are considered experimental, investigational, and unproven due to insufficient evidence in the peer reviewed published literature:
    a. Bio-artificial transplants, such as the transplant of a total artificial heart
    b. Xenotransplants, such as the transplant of animal tissue into human
    c. Allogeneic (ablative and non-myeloablative) hematopoietic stem cell transplantation is considered investigational and not medically necessary for the treatment of all genetic diseases not listed above including, but not limited to cystic fibrosis, and all acquired anemias not specifically identified above as medically necessary.
    d. Autologous hematopoietic stem cell transplantation is considered investigational and not medically necessary for the treatment of all genetic diseases including, but not limited to cystic fibrosis, and all acquired anemias.
    e. A planned tandem allogeneic hematopoietic stem cell transplantation or autologous hematopoietic stem cell transplantation is considered investigational and not medically necessary for all genetic diseases and for all acquired anemias.

f. A second or repeat allogeneic (ablative or non-myeloablative) hematopoietic stem cell transplant due to persistent, progressive or relapsed disease is considered investigational and not medically necessary.
g. Hematopoietic stem cell harvesting for a future but unscheduled transplant is considered investigational and not medically necessary.
h. Autologous hematopoietic stem cell mobilization and pheresis is considered investigational and not medically necessary for the treatment of a genetic disease when the medically necessary criteria above are not met.

3. Services or supplies related to an excluded or non-reimbursable procedure/service. This includes, but is not limited to experimental or investigational procedures and devices.
4. Services or supplies for a donor that are not directly related to the organ transplant.
5. Services relating to collection, preservation and potential future use of umbilical cord blood.
6. Donor related medical or other expenses of a transplant when the recipient is not a member.
7. Coverage is not provided for organs sold rather than donated to a recipient.
8. Lodging is not covered even when related to receiving any medical service, unless the patient is an INTEGRITY for Duals or Dual CONNECT member. See the Transplant Transportation & Lodging Policy for additional guidance.
9. Transplant procedures are considered investigational in all other situations not mentioned in this policy.

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Authorization Request Forms

Access prior authorization request forms by visiting Neighborhood's website at www.nhpri.org.

1. Click on Providers
2. Click on Provider Resources
3. Click on Forms
4. Click on "Click here for a list of prior authorization request forms" – forms are listed alphabetically.

A phone messaging system is in place for requests/inquiries both during and outside of business hours. Providers can call 1-800-963-1001 for assistance.

Covered Codes: For information on coding, please reference the Authorization Quick Reference Guide.

CMP Number:	#081
CMP Cross Reference:	
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Effective Dates:	10/14/26

Neighborhood reviews clinical medical policies on an annual basis.

Disclaimer:
Neighborhood has developed medical policies to assist us in administering health benefits. This medical policy is made available to you for informational purposes only and does not constitute medical advice. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Members should always consult their physician before making any decisions about medical care. Treating providers are solely responsible for medical advice and treatment of members. Benefits and eligibility are determined by the member's coverage plan; a member's coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.