

BENEFIT COVERAGE POLICY



Title: BCP-17 Retransplantation and Pediatric Transplantation

Effective Date: 04/01/2023

v.3

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

- The terms of the applicable benefit document in effect on the date of service.
- Any applicable laws and regulations.
- Any relevant collateral source materials including coverage policies.
- The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

The Health Plan considers renal transplantation for patients under the age of 18 years old as medically necessary if the clinical determination guidelines below are met.

The Health Plan considers cardiac transplantation for patients under the age of 18 years old as medically necessary if the clinical determination guidelines below are met.

The Health Plan considers liver transplantation for patients under the age of 18 years old as medically necessary if the clinical determination guidelines below are met.

All transplant related services require prior approval for coverage of Covered Health Services provided at a Health Plan-designated transplant facility (see section 5.0 for exceptions). Contact the Health Plan Transplant Case Manager to verify if a provider is contracted as a designated transplant facility.

Non-network services are not covered.

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage and exclusions.

2.0 Background:

A. Pediatric Renal Transplantation.

Kidney transplantation (KT) is the gold standard for renal replacement therapy in pediatric patients with end-stage renal disease. Recently, it has been observed that the outcome of pediatric KT is nearly identical to that in adults owing to the development and application of a variety of immunosuppressants and newer surgical techniques. However, owing to several differences in characteristics between children and adults, pediatric KT requires that additional information be learned and is associated with added concerns. These differences include post-KT complications, donor-recipient size mismatch, problems related to growth, and nonadherence to therapy, among others.

B. Pediatric Cardiac Transplantation.

Pediatric cardiac transplantation is standard of care for children with end-stage heart failure and cardiomyopathy. The diverse age range, diagnoses, and practice variations continue to challenge the development of evidence-based practices and new technologies. Outcomes in the most recent era are excellent, especially with the more widespread use of ventricular assist devices (VADs). Waitlist mortality remains high and knowledge of risk factors for death while waiting and following transplantation contributes to decision-making around transplant candidacy and timing of listing. The biggest gap impacting both waitlist and overall survival remains mechanical support options for infants and patients with single ventricle physiology. Though acute rejection has decreased progressively, both diagnosis and management of antibody-mediated rejection has become increasingly challenging and complex, as has the ability to understand the implication of anti-HLA antibodies detected both pre- and post-transplantation—including when and how to intervene. Trends in immunosuppression protocols include more use of induction therapy and steroid avoidance or withdrawal protocols. Common long-term morbidities include renal insufficiency, which can be mitigated with surveillance and renal-sparing strategies, and infections. Functional outcomes are excellent, but significant psychosocial challenges exist in relation to neurodevelopment, nonadherence, and transition from child-centered to adult-centered care. Cardiac allograft vasculopathy (CAV) remains a barrier to long-term survival, though it is more apparent that objective evidence of an impact on the allograft is important with regards to impact on outcomes. Retransplantation is rare in pediatric heart transplant recipients. Pediatric heart transplantation continues to evolve in order to address the challenges of the diverse group of patients that reach end-stage heart failure during childhood.

C. Pediatric Liver Transplantation.

Pediatric Liver transplantation has been very successful in treating children with end-stage liver disease and offers the opportunity for a long healthy life. The main indications for liver transplantation in the pediatric population are as follows: (1) Extra-hepatic cholestasis: biliary atresia. (2) Intra-hepatic cholestasis: sclerosing cholangitis; Alagille's syndrome; non-syndromic paucity of intrahepatic bile ducts; and progressive familial intrahepatic cholestasis. (3) Metabolic diseases: Wilson's disease; α 1-antitrypsin deficiency; Crigler-Najjar syndrome; inborn error of bile acid metabolism; tyrosinemia; disorders of the urea cycle; organic acidemia; acid lipase defect; oxaluria type I; and disorders of carbohydrate metabolism. (4) Acute liver failure. (5) Others: primary liver tumor and cystic fibrosis. Patient survival has continued to improve as a result of improvements in medical, surgical, and anesthetic management, organ availability, immunosuppression, and identification and treatment of postoperative complications.

D. Renal Retransplantation.

The life expectancy after renal retransplantation is less than that after primary transplantation, but the difference is mainly due to an increased early postoperative mortality. The prognosis after retransplantation is greatly improved if the second kidney is from a related donor. The prognosis is likewise improved if a longer period of time has elapsed between the two transplantations. 20% of kidney transplants every year are re-transplants. There are many reasons why a kidney transplant can fail, including clots, fluid collection, infection, side effects of medicines, donor kidney problems, recurrent disease, acute rejection, and chronic rejection.

E. Cardiac Retransplantation.

Cardiac retransplantation is associated with inferior short-term and long-term survival when compared with primary heart transplantation, and its use remains controversial, although less so in the pediatric heart transplant population. The most common indications for retransplantation are CAV and allograft failure. While primary graft failure is the most common reason in the first month after heart transplantation, CAV is the most common cause after the first year. Other reasons include transplant rejection or valvular disease.

F. Liver Retransplantation.

Improvements in operative technique, immunosuppression, and organ procurement have done much to enhance the probability that the liver recipient will survive long term. Nevertheless, failure of a hepatic allograft continues to be a serious risk facing the liver recipient. Because no effective method of extracorporeal support is available for these patients, undergoing retransplantation is the only alternative that offers the potential for long-term survival.

G. Pancreas Retransplantation.

Pancreas retransplantation is a safe procedure with acceptable graft survival that should be proposed to diabetic patients who have lost their primary grafts. In the past, pancreas retransplantation was considered to have a high risk of technical failure and rejection compared with kidney retransplantation, so it was rarely performed. However, pancreas retransplantation is now more common, and positive outcomes with repeat transplantation have been reported. Rejection remains an important risk factor for pancreas re-transplant graft failure. Pancreas retransplantation in an appropriate patient is the best option for the preservation of kidney allograft function in simultaneous pancreas-kidney transplant recipients with isolated pancreas graft failure. With modern era improvements in surgical techniques, immunosuppression and graft monitoring have overall added to better outcomes.

3.0 Clinical Determination Guidelines:

A. Pediatric Transplants are *eligible for coverage* as follows:

1. Pediatric Solid Organ Transplants:

a. Pediatric Renal Transplant.

- i. Pediatric (less than 18 years of age).
- ii. Pediatric patient has met and been approved for Health Plan's Pre-Transplant policy criteria.
- iii. Pediatric patient has been accepted by the transplanting institution for Renal Transplant.

b. Pediatric Cardiac Transplant.

- i. Pediatric (less than 18 years of age).
- ii. Pediatric patient has met and been approved for Health Plan's Pre-Transplant policy criteria.
- iii. Pediatric patient has been accepted by the transplanting institution for Cardiac Transplant.

c. Pediatric Liver Transplant.

- i. Pediatric (less than 18 years of age):
- ii. Pediatric patient has met and been approved for Health Plan's Pre-Transplant policy criteria.
- iii. Pediatric patient has been accepted by the transplanting institution for Liver Transplant.

B. Retransplantations are eligible for coverage as follows:

1. Member should have received prior approval for pre-transplant services (evaluation, outpatient diagnostics, and labs) at a Health Plan-designated transplant facility linked to one of the transplant networks: Emerging Therapy Solutions (ETS), or Cigna LifeSource. If a member is not receiving services at a Health Plan-designated facility, the member is redirected to a designated facility (see section 5.0 for exceptions); and
2. Member has completed an evaluation and has been accepted by the transplant committee at a designated transplant facility. Documentation must include a summary letter from the transplant center indicating acceptance and outlining the preoperative tests and their results; and
3. Member meets transplant institution's protocol eligibility criteria,

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = EPO/PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union & Union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union Only; 8 = ASO group L0002184; 9 = ASO group L0002237, 10 = ASO L0002193.

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Reference
Renal			
50300	Donor nephrectomy from cadaver donor, unilateral or bilateral	Y	Transplantation Services
50320	Donor nephrectomy; open, from living donor	Y	Transplantation Services
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation	N	Transplantation Services
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation	N	Transplantation Services
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation, venous anastomosis, each	N	Transplantation Services
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	Y	Transplantation Services
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy	Y	Transplantation Services
50370	Removal of transplanted renal allograft	N	Transplantation Services
50547	Laparoscopy, surgical; donor nephrectomy, from living donor	Y	Transplantation Services
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and	N	Transplantation Services

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Reference
	rehabilitative services, and the number of days of pre-and post-transplant care in the global definition		
Cardiac			
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation	N	Transplantation Services
33940	Donor cardiectomy (including cold preservation)	Y	Transplantation Services
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation	N	Transplantation Services
33945	Heart transplant, with or without recipient cardiectomy	Y	Transplantation Services
Liver			
47133	Donor hepatectomy (including cold preservation) from cadaver donor	Y	Transplantation Services
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	Y	Transplantation Services
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split	N	Transplantation Services
47146	Donor hepatectomy (including cold preservation) from cadaver donor	Y	Transplantation Services
Pancreas			
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells	Y	Transplantation Services
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation	Y	Transplantation Services
48554	Transplantation of pancreatic allograft	Y	Transplantation Services
48556	Removal of transplanted pancreatic	Y	Transplantation Services

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Reference
	allograft		
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor	N	Transplantation Services
S2102	Islet cell tissue transplant from pancreas; allogeneic	Y	Transplantation Services
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre-and post-transplant care in the global definition	N	Transplantation Services

NON-COVERED CODES		
Code	Description	Benefit Plan Reference/Reason
C1824	Generator, cardiac contractility modulation (implantable)	Experimental/investigational/unproven
0018M	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	Experimental/investigational/unproven
0087U	mRNA gene expression profiling of genes in heart transplant biopsy tissue to evaluate risk of rejection	Experimental/investigational/unproven
0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection	Experimental/investigational/unproven
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA	Experimental/investigational/unproven

5.0 Unique Configuration/Prior Approval/Coverage Details

ASO group L0001631 and L0002237 plans have a Travel and Lodging Benefit included in the Transplant Benefit (see SPDs for details).

6.0 References, Citations & Resources:

InterQual®, subset Transplantation, Liver, 4-15-2022

InterQual®, subset Transplantation, Cardiac, 4-15-2022

InterQual®, subset Transplantation, Renal, 4-15-2022

Cho M. H. (2018). Pediatric kidney transplantation is different from adult kidney transplantation. *Korean Journal of pediatrics*, 61(7), 205–209. Retrieved November 13, 2020, from <https://doi.org/10.3345/kjp.2018.61.7.205>.

Dipchand A. I. (2018). Current state of pediatric cardiac transplantation. *Annals of cardiothoracic surgery*, 7(1), 31–55. Retrieved November 6, 2020, from <https://doi.org/10.21037/acs.2018.01.07>.

Spada, M., Riva, S., Maggiore, G., Cintonino, D., & Gridelli, B. (2009). Pediatric liver transplantation. *World journal of gastroenterology*, 15(6), 648–674. Retrieved November 13, 2020, from <https://doi.org/10.3748/wjg.15.648>.

Shaw, B. W., Jr, Gordon, R. D., Iwatsuki, S., & Starzl, T. E. (1985). Retransplantation of the liver. *Seminars in liver disease*, 5(4), 394–401. Retrieved November 13, 2020, from <https://doi.org/10.1055/s-2008-1040638>.

Tushla, L. E. (2019, February 07). When a Transplant Fails. Retrieved November 13, 2020, from https://www.kidney.org/transplantation/transaction/TC/summer09/TCsm09_TransplantFails.

Husberg, B. S., & Starzl, T. E. (1974). Proceedings: The outcome of kidney retransplantation. *Archives of surgery (Chicago, Ill.: 1960)*, 108(4), 584–587. Retrieved November 13, 2020, from <https://doi.org/10.1001/archsurg.1974.01350280184030>.

Barghash, M. H., & Pinney, S. P. (2020). Heart Retransplantation: Candidacy, Outcomes, and Management. *Current transplantation reports*, 7(1), 12–17. Retrieved November 13, 2020, from <https://doi.org/10.1007/s40472-019-00257-y>.

Parajuli, S., Arunachalam, A., Swanson, K. J., Aziz, F., Garg, N., Bath, N., Redfield, R. R., Kaufman, D., Djamali, A., Odorico, J., & Mandelbrot, D. A. (2019). Pancreas Retransplant After Pancreas Graft Failure in Simultaneous Pancreas-kidney Transplants Is Associated With Better Kidney Graft Survival. *Transplantation direct*, 5(8), e473. <https://doi.org/10.1097/TXD.0000000000000919>

7.0 Associated Documents [For internal use only]:

Policies & Procedures (P&Ps) - MMP-02 Transition/Continuity of Care; UMPP-02 Peer-to-Peer Conversations; MMP-09 Benefit Determinations.

Standard Operating Procedures (SOPs) – MMS-03 Algorithm for Use of Criteria for Benefit Determinations; MMS-05 Completing an HCN; MMS-09 Case Management Referrals, MMS-10 Pre-Transplant Process; MMS-11 Transplant Event and Listing; MMS-12 Post-Transplant Process, MMS-48 Outpatient Service for Transplant, MMS-49 CCA Transplant Event and Listing

Sample Letters – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Specific Exclusion Denial Letter.

Forms – Out of Network/ Prior Authorization; High Cost Notification Form; Transplant Travel and Lodging Reimbursement Form.

Other – Transplant Network contracts with Cigna LifeSource and Emerging Therapy Solutions (ETS).

8.0 Revision History:

Original Effective Date: 01/01/2021

Next Review Date:

Revision Date & Approval	Reason for Revision
10/20	Policy created
01/22	Annual review. Removed Interlink references, updated InterQual references, and updated Code 50370 from PA to C. Changed effective date to 04/01/2022 per BCC
1/23	Annual review, updated LifeTracs name to Emerging Therapy Solutions (ETS) removed InterLink, updated associated SOP's to include CCA Transplant processes, added L0002193 to section 4.0, Updated language in section 5.0: ASO group L0001631 and L0002237 plans have a Travel and Lodging Benefit included in the Transplant Benefit (see SPDs for details). Moved 0088U and

Revision Date & Approval	Reason for Revision
	0118U from covered to NC code section, updated InterQual references.