

BENEFIT COVERAGE POLICY



Title: BCP-17 Retransplantation and Pediatric Transplantation

Effective Date: 04/01/2021

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, non-adherence, 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 have 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 re transplantation 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 patient 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 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 improvement 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: Interlink, LifeTrac, 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.

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Reference
Renal			
50300	Donor nephrectomy from cadaver donor, unilateral or bilateral	Y	Professional fees for medical and surgical services
50320	Donor nephrectomy; open, from living donor	Y	Professional fees for medical and surgical services
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation	N	Professional fees for medical and surgical services
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation	N	Professional fees for medical and surgical services
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation, venous anastomosis, each	N	Professional fees for medical and surgical services
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	Y	Professional fees for medical and surgical services
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy	Y	Professional fees for medical and surgical services
50370	Removal of transplanted renal allograft	Y	Professional fees for medical and surgical services
50547	Laparoscopy, surgical; donor	Y	Professional fees for

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Reference
	nephrectomy, from living donor		medical and surgical 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	Professional fees for medical and surgical services
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	Professional fees for medical and surgical services
33940	Donor cardiectomy (including cold preservation)	N	Professional fees for medical and surgical 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	Y	Professional fees for medical and surgical services
33945	Heart transplant, with or without recipient cardiectomy	Y	Professional fees for medical and surgical services
Liver			
47133	Donor hepatectomy (including cold preservation), from cadaver donor	Y	Professional fees for medical and surgical services
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	Y	Professional fees for medical and surgical 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	N	Professional fees for medical and surgical services

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Reference
	the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split		
47146	Donor hepatectomy (including cold preservation), from cadaver donor	Y	Professional fees for medical and surgical services
Pancreas			
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells	Y	Professional fees for medical and surgical services
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation	Y	Professional fees for medical and surgical services
48554	Transplantation of pancreatic allograft	Y	Professional fees for medical and surgical services
48556	Removal of transplanted pancreatic allograft	Y	Professional fees for medical and surgical services
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor	N	Professional fees for medical and surgical 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	Professional fees for medical and surgical services

NON-COVERED CODES		
Code	Description	Benefit Plan Reference/Reason
C1824	Generator, cardiac contractility modulation (implantable)	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

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
S2102	Islet cell tissue transplant from pancreas; allogeneic	Experimental/ Investigational/Unproven

5.0 Unique Configuration/Prior Approval/Coverage Details

Under fully insured DSP (prefix of Product ID) PPO plans, Kidney transplants do not have to be done at designated facilities.

Self-funded ASO group L0001631 plans include a Transplant Travel and Lodging Benefit (see specific benefit documents for details).

6.0 References, Citations & Resources:

InterQual®, subset Transplantation, Liver, 4-17-2020

InterQual®, subset Transplantation, Cardiac, 4-17-2020

InterQual®, subset Transplantation, Renal, 4-17-2020

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>.

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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>.

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7.0 Associated Documents [For internal use only]:

Policies & Procedures (P&Ps) - MMP-02 Transition/Continuity of Care; MMP-06 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 a HCN; MMS-10 Pre-Transplant Process; MMS-11 Transplant Event and Listing; MMS-12 Post-Transplant Process.

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, Interlink, and LifeTrac.

8.0 Revision History:

Original Effective Date: 01/01/2021

Next Review Date: 04/01/2022

Revision Date & Approval	Reason for Revision
10/23/2020	Policy created