BENEFIT COVERAGE POLICY

Title: BCP-51 Renal Transplantation

Effective Date: 04/01/2024

v.8

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 covers kidney transplantation from a deceased or living donor as medically necessary in patients with end stage renal disease (ESRD) and when the Clinical Determination Guidelines below are met. Repeat transplantation due to acute or chronic graft failure is considered medically necessary.

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 the member's benefit coverage document for specific benefit descriptions, guidelines, coverage, and exclusions.

2.0 Background:

Chronic renal failure is slowly progressive over a number of years and most often results from any disease that causes gradual destruction of the internal structures of the kidneys. It can range from mild dysfunction to severe kidney failure, termed end-stage renal disease (ESRD). Progression of kidney disease may be so gradual that symptoms do not occur until kidney function is less than 1/10th of normal. Because of the reversible nature of acute renal failure, all patients with this diagnosis should be supported with dialysis, at least for some period of time, to allow the return of renal function.

Patients with ESRD have three options for renal replacement therapy (RRT): 1) hemodialysis; 2) chronic ambulatory peritoneal dialysis; or 3) transplantation. The choice should be based on the relative risks and benefits. With the increasing appreciation that transplantation results are superior to those of chronic dialysis, the indications for transplantation have been broadened. Improvements in peri-operative care and immunosuppression have allowed many patients who would previously have been denied transplantation consideration as acceptable candidates. The best recipients for transplantation are young individuals whose renal failure is not due to a systemic disease that will damage the transplanted kidney or cause death from extra-renal causes.

The time a patient has spent on dialysis is an independent predictor of a poorer outcome from renal transplantation. Pre-emptive renal transplantation generally leads to better outcomes than transplantation after dialysis is initiated and should be pursued in most cases for live donor transplants. The current shortage of cadaveric kidneys makes it unlikely that pre-emptive transplants will be a practical option for recipients of cadaveric kidney transplants.

There are three sources of donor kidneys for kidney transplantation:

1. Living related donors.
2. Living unrelated donors.
3. Cadaveric donors.

3.0 Clinical Determination Guidelines:

See InterQual Renal Transplantation for 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 Cost Share Reference**
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
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each	N	Transplantation Services
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral 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
50547	Laparoscopy, surgical; donor nephrectomy, from living donor	Y	Transplantation Services
S2152	Solid organ(s), complete or segmental, single organ or combination of organs;	N	Transplantation Services

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Cost Share Reference**
	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		

NON-COVERED CODES		
Code	**Description**	**Benefit Plan Reference/Reason**
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 Terms & Definitions:

Active candidate – A candidate on the waiting list who is currently suitable for transplantation and eligible to receive organ offers.

Allograft – The transplant of an organ or tissue from one individual to another. Also called allogeneic or homograft.

Cadaveric (deceased) donor **–** An individual from whom an organ is recovered for transplant after declaration of death.

Chronic kidney disease (CKD) – Also referred to as chronic renal insufficiency, chronic renal failure. Terms describing the continuum of increasing renal dysfunction and decreasing glomerular filtration rate (GFR). Because of the progressive nature of kidney disease, these terms represent successive stages of disease in most patients.

Stage	Description	GFR mL/min/1.73m^2
1	Slight kidney damage with normal or increased filtration	Greater than 90
2	Mild decrease in kidney function	60 - 89
3	Moderate decrease in kidney function	30-59
4	Severe decrease in kidney function	15-29

Stage	Description	GFR mL/min/1.73m^2
5	Kidney failure; requiring dialysis or transplantation	Less than15

Dialysis – The process by which metabolic waste products are removed by cleansing the blood directly through extracorporeal filtration membranes (hemodialysis) or indirectly by diffusion of waste products through the peritoneal membranes into instilled fluids (peritoneal dialysis).

Designated facility – A facility that has entered into an agreement on behalf of the facility and its affiliated staff with the Health Plan or with an organization contracting on our behalf, to render covered health services for the treatment of specified diseases or conditions. A designated facility may or may not be located within a member's geographical area. The fact that a hospital is a network hospital does not mean that it is a designated facility.

End-stage renal disease (ESRD) – The stage in chronic renal disease in which renal replacement therapy, dialysis, or kidney transplantation is needed to sustain life. Treated chronic kidney failure is generally an irreversible state. The glomerular filtration rate is usually less than 20 ml/min. The most common cause of ESRD is diabetes mellitus. Other diseases that may lead to ESRD include hypertension, polycystic kidneys, nephrosclerosis, chronic pyelonephritis, glomerulonephritis, kidney stones, renal cell carcinoma, and Wilm's tumor.

Glomerular filtration rate (GFR) – Measure of kidney function, which is used to determine the stage of kidney disease and is important for the doctor to determine a patient's treatment plan. Children reach adult values for mean GFR by approximately two years of age. The normal mean GFR for young adults is approximately 120-130 mL/minute per 1.73m2 and declines with age. The following factors are used in calculating GFR:

- Age – GFR decreases with age.
- Serum creatinine – Usually between 0.8 and 1.6 but may be higher or lower. Measures waste product in the blood that comes from muscle activity. The kidneys normally remove creatinine from the blood. As kidney function slows down, creatinine level goes up.
- Gender – Men usually have more muscle mass than women, so the calculation is adjusted.
- Race – Afro-Americans tend to have more muscle mass than other ethnicities, so the calculation is adjusted.

Graft failure – A significant complication following an allogeneic transplant in which a transplanted organ or tissue loses function. Graft failure statistics are recorded at one month, one year, and three years post-transplant.

Graft rejection – A process in which the immune system of the transplant recipient attacks the transplanted organ or tissue. Graft rejection is the major cause of graft failure. There are three types of rejection:

- Hyperacute rejection – usually occurs within the first 24 hours of transplantation with a high risk of rapid clumping of red blood cells.
- Acute rejection – usually begins after the first week of transplantation with the risk at its highest in the first three months after transplantation. Occurs in approximately 10-20% of kidney transplants.
- Chronic rejection – occurs months to years following transplantation with risk factors identified such as young recipient age, Afro-American race, pre-sensitization (pregnancies, blood transfusions, or failed transplants), and acute rejection episodes.

Inactive candidate – A candidate who is temporarily unavailable or unsuitable for transplantation and appears as inactive on the waiting list.

Kidney Allocation System (KAS) – A new kidney allocation system (KAS) was developed by the Organ Procurement and Transplantation Network (OPTN) Kidney Transplantation Committee in response to higher than necessary discard rates of kidneys, variability in access to transplants for

candidates who are harder to match due to biologic reasons, and a matching system that results in unrealized life years and high re- transplantation rates. The new KAS was implemented in December 2014.

The KAS includes the following changes:

- Replacement of the current kidney donor quality metric with the Kidney Donor Profile Index (KDPI)
.
- Adult transplant candidates will receive an Expected Post Transplant Survival (EPTS) score.
- Allocation rules will use the KDPI for donors and the EPTS score for longevity matching between donors and recipients.
- Sensitized candidates will be given increased priority through a sliding scale points system for calculated panel reactive antibodies (CPRA) and regional and national sharing for very highly sensitized candidates.
- Pre-registration dialysis time will be included in a candidate's waiting time.
- Increased access to donor kidneys for blood type B candidates.
- Elimination of the payback system.
- Other variances are being eliminated with the implementation of the new system.

Kidney Paired Donation (KPD) – The donation and receipt of human kidneys under the following circumstances:

- An individual (the first living donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but the first living donor is biologically incompatible as a donor for the first patient.
- A second individual (the second living donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but the second living donor is biologically incompatible as a donor for the second patient.
- The first living donor is biologically compatible as a donor of a kidney for the second patient, and the second living donor is biologically compatible as a donor of a kidney for the first patient. If there is any additional donor-patient pair as described above, each living donor in the group of donor-patient pairs is biologically compatible as a living donor of a kidney for a patient in the group.
- All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive the kidneys, respectively, according to biological compatibility within the group.

Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred for the donation of the kidneys.

Living donor – A living individual from whom at least one organ is recovered for transplantation. Living donor kidneys have become more common and although there is potential for donor morbidity associated with the procedure, most transplant centers regard living donors as the preferred donation modality. Living donors can be related or unrelated to the recipient. The benefit to the recipient of a live donor organ must outweigh the risks to the donor.

National Organ Transplant Act (NOTA) **–** Act passed by the Congress of the U.S. in 1984 that called for a national network to coordinate the allocation of organs and collect clinical data about organ donors, transplant candidates, and transplant recipients.

Nephropathy – Any disease affecting the kidneys, i.e., diabetic nephropathy, hypertensive nephropathy.

Nephrosclerosis – Kidney disease that is usually associated with hypertension; sclerosis of the renal arterioles reduces blood flow which can lead to kidney failure and heart failure.

Nephrosis – Inflammation of the kidney.

Organ Procurement and Transplantation Network (OPTN) **–** A unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system. Efforts are focused on patients with the goals to:

- Increase the number of and access to transplants.
- Improve survival rates after transplantation.

Promote patient safety and efficient management of the system by maintaining transplant policies and bylaws.

Plasmapheresis – A blood purification procedure used to treat several autoimmune diseases. Also known as therapeutic plasma exchange.

Polycystic kidney disease (PKD) – Kidney disease characterized by enlarged kidneys containing many cysts; often leading to kidney failure.

Preemptive transplant – Patients who are nearing ESRD can receive a transplant prior to initiating dialysis. Transplantation is performed prior to the need for dialysis has a survival advantage for the recipient and is common for recipients of living donor kidneys.

Regions (Transplant) – For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the membership is divided into 11 geographic regions. Members belong to the Region in which they are located. The Regions are as follows:

- Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont
- Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO.
- Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
- Region 4: Oklahoma and Texas
- Region 5: Arizona, California, Nevada, New Mexico, and Utah
- Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington
- Region 7: Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin
- Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming
- Region 9: New York and Western Vermont
- Region 10: Indiana, Michigan, and Ohio
- Region 11: Kentucky, North Carolina, South Carolina, Tennessee, and Virginia

Scientific Registry of Transplant Recipients (SRTR) - Provides reports and data on solid organ transplantation.

United Network for Organ Sharing (UNOS) **–** Nonprofit organization that established a computerized database in 1977 that coordinates U.S. organ transplant activities. Their website contains information and statistics about organ transplantation by region, state and transplant center. UNOS was awarded the contract to develop the requirements for the operation of the OPTN since 1986.

7.0 References, Citations & Resources:

1. InterQual – Renal Transplantation 3-31-2023.
2. DaVita.com: GFR Calculator. Available at URL address: http://www.davita.com/gfr-calculator/
3. Organ Procurement and Transplantation Network (OPTN), Policies Administrative Rules and Definitions, 10/24/2019. Available at URL address: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08
4. United Network for Organ Sharing (UNOS). Available at URL address: https://www.unos.org/.

8.0 Associated Documents [For internal use only]:

Benefit Coverage Policies - BCP-17 Retransplantation and Pediatric Transplantation BCP-33 Pre-Transplant Services

Policies and Procedures (P&Ps) - MMP-02 Transition and Continuity of Care MMP-09 Benefit Determinations UMP-02 Peer to Peer Conversations

Standard Operating Procedures (SOPs) –MMS-03 Algorithm for Use of Criteria for Benefit Determinations MMS-05 Completing a High Cost Notification Form MMS-09 Case Management Referrals MMS-48 CCA Outpatient Services for Transplant MMS-49 CCA Transplant Event and Listing

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

Form –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).

9.0 Revision History:

Original Effective Date: 02/13/2008

Next Review Date: 02/19/2024

Revision Date	Reason for Revision
2/16	Annual review with revisions: Title changes – removed references to Medical Resource Management (MRM) and changed to "Medical Policy" with the Responsible Dept assigned to Case Management team. Removed references to Sparrow PHP, Healthy Michigan, MI Child, and MDHHS. Product Application: added reference to COC definitions related to policy. Clinical Determination Guidelines: # 1-7 is being standardized in all of the transplant policies. ICD-10 codes added. Terms Associated with Services: added additional terminology. References and Resources: updated.
2/17	Annual review with revisions – Changed from MRM Medical Policy MP 012 to Benefit Coverage Committee Policy formatting. Added criteria for use of medical marijuana. Revision of 10. a. specified stage 4 GFR for pediatrics, added Kidney Allocation System (KAS)
1/18	Annual review by BCC, annual review by QI/MRM 2/14/18.
1/19	Annual review by BCC, annual renewal by QI/MRM 2/13/19. Citations updated.
11/19	Annual review; new codes added; 0088U and 0118U, code removed 50380. Annual review off-cycle (12/11/19) due to change in QI/MRM Cmte. to MRM Cmte. meeting quarterly (March 2020).
4/21	Annual review; removed medical criteria, added reference to InterQual criteria; updated associated documents; removed ICD-10 code table; updated codes, removed backbench codes other than those on InterQual; aligned codes with

Revision Date	Reason for Revision
	InterQual criteria; changed policy title from “Kidney” to “Renal” Transplantation to align with InterQual.
4/22	Annual review, formatting changes. Removed Interlink references. Updated InterQual reference. Effective date changed from 7/1/22 to 4/1/22.
1/23	Annual review, Updated LOB: added L0002193, Removed Interlink from section 8.0, updated LifeTracs name to Emerging Transplant Solutions, Updated SOP's to include CCA Transplant Process SOPs, 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) Removed language from 5.0 re: DSP plan, plan discontinued. Moved 0088U and 0118U from covered to NC code section.
1/24	Annual review, added codes 50328 and 50329, updated InterQual reference.