BENEFIT COVERAGE POLICY

Title: BCP-51 Kidney Transplantation

Effective Date: 04/01/2019

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:

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 member's benefit coverage document for specific benefit description, 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 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:

A. Kidney transplantation is considered medically necessary when all the following applicable criteria below are met:

1. One evaluation per transplant approval.

   Note: A second opinion consult only would be approved to determine candidacy at a Health Plan designated transplant facility if a second transplant evaluation is requested and the member has been previously turned down for transplant.

2. Documentation of compliance with medical management; **and**

3. Member should have received prior authorization/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 will be redirected to a designated facility; **and**

4. Social work evaluation indicating member does not have any unresolvable psychosocial problems which may interfere with compliance with transplant management; **and**

5. 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**

6. Member meets transplant institution's protocol eligibility criteria regarding age; **and**

7. Attending physician has determined there are no prohibitive risk factors or absolute contraindications for transplant recipients, which include but are not limited to ANY of the following:

   a. Over 70 years of age with severe co-morbidities; **or**

   b. Ongoing alcohol or drug abuse (members with a history of using alcohol, tobacco or other substances of abuse must be abstinent for a minimum of three consecutive months before being considered an eligible transplant candidate as determined by random urine drug screens with negative results). Use of marijuana for medical purposes requires written approval from the referring specialist (cardiologist, nephrologist, etc.) and transplant eligibility is subject to the transplanting institution's criteria; **or**

   c. Metastatic cancer; **or**

   d. Ongoing or recurring infections that are not effectively treated; **or**

   e. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery; **or**

f. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured; **or**

g. Demonstrated patient noncompliance, which places the transplanted organ at risk by not adhering to medical recommendations; **or**

h. Potential complications from immunosuppressive medications are unacceptable to the patient; **or**

i. Acquired immune deficiency syndrome (AIDS), unless ALL the following are noted:

i. CD4 count greater than 200 cells/mm^3 for greater than six months.

ii. HIV-1 RNA undetectable.

iii. On stable anti-retroviral therapy greater than three months.

iv. No other complications from AIDS (e.g., opportunistic infection such as aspergillus, tuberculosis, coccidiodomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm).

j. Meeting all other criteria for kidney transplantation.

8. Severity of disease:

a. On hemodialysis or continuous ambulatory peritoneal dialysis (CAPD); **or**

b. Has severe chronic renal failure (defined as a creatinine clearance of less than 30 ml/min.) with anticipated deterioration to end stage renal disease, where member is seeking precertification for cadaveric kidney transplantation; **or**

c. Has end stage renal disease, evidenced by a creatinine clearance below 20 ml/min/1.73m^2 or development of symptoms of uremia, and member is seeking precertification for a living donor kidney transplantation.

9. Indications for repeat kidney transplantation:

a. Acute or chronic graft failure.

10. Pediatric renal transplantation:

a. Patients less than 18 years of age with stage 4 CKD w/ estimated GFR <30 mL/min/1.73m^2. Pre-emptive transplant is better for children than waiting for dialysis.

11. ABO incompatibility or Positive cross-match:

a. Recent studies have demonstrated than an ABO mismatched living donor transplant may result in survival rates close to those achieved with compatible grafts. Treatment protocol may include pre-transplant plasmapheresis followed by immunosuppressive medication, antibody therapy, and/or splenectomy with postoperative anticoagulant therapy.

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union.

COVERED CODES

Code	Description	Prior Approval	COC Reference
50300	Donor nephrectomy from cadaver donor, unilateral or bilateral	Y	Benefits and Coverage, Transplantation Services
50320	Donor nephrectomy; open, from living donor	Y	Benefits and Coverage, Transplantation Services
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation	Y	Benefits and Coverage, Transplantation Services
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation	Y	Benefits and Coverage, Transplantation Services
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation, venous anastomosis, each	Y	Benefits and Coverage, Transplantation Services
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation, arterial anastomosis, each	Y	Benefits and Coverage, Transplantation Services
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each	Y	Benefits and Coverage, Transplantation Services
50340	Recipient nephrectomy (separate procedure)	Y	Benefits and Coverage, Transplantation Services
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	Y	Benefits and Coverage, Transplantation Services
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy	Y	Benefits and Coverage, Transplantation Services
50370	Removal of transplanted renal allograft	Y	Benefits and Coverage, Transplantation Services
50380	Renal autotransplantation, reimplantation of kidney	Y	Benefits and Coverage, Transplantation Services
50547	Laparoscopy, surgical; donor nephrectomy, from living donor	Y	Benefits and Coverage, Transplantation Services
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor	N	Benefits and Coverage, 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	Benefits and Coverage, Transplantation Services

ICD-10 DIAGNOSIS CODES	
Code	**Description**
N18.5	Chronic kidney disease, stage V
N18.6	End stage renal disease
T86.10 – T86.19	Complications of kidney transplant…

5.0 Unique Configuration/Prior Approval/Coverage Details:

Under DSP plans, kidney transplants do not have to be done at designated facilities.

SPD, SHD, SHE, SSD, SSE, and ASO group L0001631 plans include a Transplant Travel and Lodging Benefit (see specific COC/SPD).

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
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 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 implementation of the new system.

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 donor 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 the 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 that 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.

Paired Kidney Donation (PKD) – 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.

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 to 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 which 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. DaVita.com: GFR Calculator. Available at URL address: http://www.davita.com/gfr-calculator/.
2. MCG Inpatient & Surgical Care, Optical Recovery Guidelines, Urology, Renal Transplant: S-1015. 22nd Edition. 01/30/2018.
3. Organ Procurement and Transplantation Network (OPTN), Policies Administrative Rules and Definitions, January 1, 2017. 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]:

Business Process Flow (BPF) – None.

Standard Operating Procedure (SOP) – MM-03 Benefit Determinations; MM-25 Transition/Continuity of Care; MM-55 Peer-to-Peer Conversations; SOP 001 Completing a HCN; SOP 007 Algorithm for

Use of Criteria for Benefit Determinations; SOP 016 Identification, Referral and Assignment of Members for Case Management Services

Desk Level Procedure (DLP) – None.

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

Form – Request Form: 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.

9.0 Revision History:

Original Effective Date: 02/13/2008

Last Approval Date: 02/18/2019

Next Review Date: 02/18/2020

Revision Date	Reason for Revision
February 2016	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.
February 2017	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)
January 2018	Annual review by BCC, annual review by QI/MRM 2/14/18.
January 2019	Annual review by BCC, annual renewal by QI/MRM 2/13/19. Citations updated.