BENEFIT COVERAGE POLICY

Title: BCP 71 Simultaneous Pancreas-Kidney Transplantation and Pancreas Alone Transplantation

Effective Date: 10/01/2018

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 simultaneous pancreas-kidney (SPK) transplantation and pancreas transplantation alone (PTA) as medically necessary for members with insulin-dependent diabetes and end-stage renal disease, who meet the criteria listed below. This includes coverage for:

- Simultaneous cadaver-donor pancreas with a living-donor kidney (SPLK) transplantation; or
- Sequential pancreas after kidney transplantation.

Non-network transplant services are not covered (see section 5.0 for exceptions).

Simultaneous pancreas-kidney transplantation and pancreas alone transplantation can only be done in an inpatient setting.

2.0 Background:

Diabetes mellitus is the most common endocrine disease worldwide and is the leading chronic disease in children. Despite the success of exogenous insulin therapy, numerous long-term sequelae develop in patients with diabetes, including end-stage renal failure, cardiovascular disease, autonomic and somatic neuropathy, and blindness. Chronically abnormal lipid metabolism, accelerated atherosclerosis, and destruction of the microvascular system result in global vascular disease, leading to amputations and premature death from myocardial infarctions and cerebrovascular accidents. Diabetes occurs in approximately 1% of the population and accounts for more than 160,000 deaths annually in the United States. According to the United States End-Stage Renal Disease (ESRD) Registry, diabetic patients between the ages of 20 and 45 who have to undergo dialysis as their only treatment option have less than 20% survival after ten years. Solitary renal transplantation with continued administration of exogenous insulin for glucose control is a good option for diabetic recipients as it has five-year survival rates approaching 70 % for cadaveric renal transplants and 85 % for living related donor (LRD) transplants; however, the diabetic state remains associated with poor patient survival.

The goal of these transplants is to produce a lasting normoglycemic state that enhances quality of life and prevents, arrests, or perhaps even reverses the otherwise inexorable progression of the

destructive effects of diabetes. As demonstrated in a number of studies, this resumption of normal glucose homeostasis achieved provides several benefits: (i) quality of life is improved since it usually removes dependence on both insulin and dialysis; (ii) recurrence of diabetic nephropathy is attenuated; (iii) diabetic retinopathy is reduced; (iv) progression of diabetic neuropathy may be halted and in some cases reversed, including improvements in autonomic neuropathy, enhancing both cardiac reflex function and gastric motility in some cases; and (v) beneficially affects patient survival even though this glycemic control is given as a late intervention in a diabetic patient's lifetime. More importantly, studies show that diabetic patients who receive a successful SPK transplant do not develop diabetic complications in their newly transplanted kidney, unlike persons with diabetes who receive a kidney transplant alone. Even diabetic vesicopathy has been shown to improve after transplantation, as well as attenuation of diabetic cardiovascular disease.

3.0 Clinical Determination Guidelines:

A. General Selection Criteria:

1. One evaluation per transplant approval.

   Note: A second opinion consult only to determine transplant candidacy would be approved 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 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).
4. 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
5. Member meets transplant institution’s protocol eligibility criteria; and
6. Transplant physician has determined there are no prohibitive risks (malignancy, systemic infection, HIV infection, cardiovascular, pulmonary or hepatic)
7. For SPK and SPLK transplantation, the following criteria must be met:
   a. Member has a creatinine clearance (Clcr), calculated by the Cockcroft-Gault formula (see Terms Associated below), of less than 20 ml/min. or a directly measured glomerular filtration rate (GFR) of less than 20 ml/min; and
   b. Member is diagnosed with ESRD and requires dialysis or is expected to require dialysis within the next 12 months.
   c. Absence of any malignant neoplasm (other than non-melanomatous skin cancer) that has a significant risk of recurrence; and
   d. Absence of uncontrolled HIV/AIDs infection, defined as:
      i. CD4 count greater than 200 cells/mm3 for more than six months; and
      ii. HIV-1 RNA (viral load) undetectable; and
      iii. No other complications from AIDS< such as opportunistic infection (e.g., aspergillus, coccidiodomycosis, resistant fungal infections, tuberculosis) or neoplasm (e.g., Kaposi’s sarcoma, non-Hodgkin’s lymphoma); and
      iv. On stable anti-viral therapy more than three months; and
   e. Absence of ongoing or recurrent active infections that cannot be adequately treated; and

f. Members with a history of alcohol, tobacco, and 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 (endocrinologist, nephrologist, etc.) and transplant eligibility is subject to the transplanting institution's criteria; and

g. Member has adequate cardiac status (e.g., no angiographic evidence of significant coronary artery disease, ejection fracture greater than or equal to 40%, no myocardial infarction within the last six months, negative stress test); and

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

8. Criteria to accrue kidney-pancreas waiting time, a candidate who is 18 years or older, must:

   a. Be registered for a Kidney-Pancreas transplant; and

   b. Qualify for kidney waiting time; and

   c. Meet one of the following criteria:

      i. Is on insulin and has a C-peptide value less than or equal to 2 ng/mL; or

      ii. Is on insulin and has a C-peptide value greater than 2ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI (28 kg/m2).

   Note: The maximum allowable BMI can change based on a report from the Pancreas Committee to UNOS and reviewed every six months. The BMI threshold cannot exceed 30 kg/m2.

9. A Pancreas Alone candidate registered on the Pancreas Alone waiting list, must have either of the following requirements:

   a. Be diagnosed with diabetes that requires insulin and have complications that cannot be well managed with conventional therapy; or

   b. Have severe pancreatic exocrine insufficiency

10. Because organ transplantation requires commitment to long term immunosuppression, the problems of Type I diabetes must be of a magnitude to justify the use of anti-rejection drugs. The complications of uncontrolled labile diabetes with severe metabolic instability must be judged to be more serious than being immunosuppressed.

11. Member must also have adequate renal function w/ a glomerular filtration rate (GFR) >70cc/min.

12. Indications for re-transplantation:

    a. Kidney – chronic allograft nephropathy, a generic term which includes the non-function of a grafted organ, chronic rejection, chronic nephrotoxicity of immunosuppressive agents, and recurrent disease.

    b. Pancreas – non-function of a grafted organ, chronic rejection and chronic allograft pancreatitis.

    c. Member must still meet eligibility criteria as described above for primary transplantation.

B. Procedures considered experimental, investigational, or unproven and not covered:

1. Partial pancreas transplantation from living donor (CPT 48999)

2. Segmental pancreas transplantation from living donor (CPT 48999)

3. Bio-artificial pancreas device (L8699)

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**
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells	Y	Benefits and Coverage; Transplantation Services
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation	Y	Benefits and Coverage; Transplantation Services
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft artery	Y	Benefits and Coverage; Transplantation Services
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each	Y	Benefits and Coverage; Transplantation Services
48554	Transplantation of pancreatic allograft	Y	Benefits and Coverage; Transplantation Services
48556	Removal of transplanted pancreatic allograft	Y	Benefits and Coverage; Transplantation Services
48999	Unlisted procedure, pancreas (only when used to report living donor pancreas transplantation, i.e., partial pancreas transplantation, segmental pancreas transplantation)	Y	Benefits and Coverage; Transplantation Services, unless determined to be Experimental/ Investigational or Unproven
50300	Donor nephrectomy, with preparation and maintenance of allograft, 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; including dissection and removal of perinephric fat diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches as necessary	Y	Benefits and Coverage; Transplantation Services
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches as	Y	Benefits and Coverage; Transplantation Services

COVERED CODES			
Code	**Description**	**Prior Approval**	**COC Reference**
	necessary		
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 (including cold preservation), from living donor	Y	Benefits and Coverage; Transplantation Services
L8699	Prosthetic implant, not otherwise specified (only when specifically used to report bio-artificial pancreas device)	Y	Benefits and Coverage; Prosthetic Devices, unless determined to be Experimental/ Investigational or Unproven
S2065	Simultaneous pancreas kidney transplantation	Y	Benefits and Coverage; Transplantation Services
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor	Y	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	Y	Benefits and Coverage; Transplantation Services

NON-COVERED CODES		
Code	**Description**	**COC Reference/Reason**
S2102	Islet cell tissue transplant from pancreas; allogeneic	Experimental/ Investigational/Unproven

5.0 Unique Configuration/Prior Approval/Coverage Details:

Under DSP (prefix of Product ID) PPO 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

Cockcroft-Gault formula - Used to calculate creatinine clearance which is now generally accepted as superior to actual measured creatinine clearance as determined by a 24-hour urine collection, due to inherent inaccuracies and collection difficulties. Calculator available at: http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault.

C-peptide - Levels of C-peptide in the blood can be measured and used as an indicator of insulin production in those cases where exogenous insulin (from injection) is present and mixed with endogenous insulin (that produced by the body) a situation that would make meaningless a measurement of insulin itself. In patients with Type I IDDM, there should be no detectable C-peptide. In patients with Type II IDDM, C-peptide levels may be normal or even high.

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.

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).

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.

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.

Pancreas/Kidney-Pancreas Allocation System – Before October 2014, there was no nationally established allocation practice for patients with diabetes and renal failure. Previous pancreas allocation policy allowed OPOs several choices on pancreas allocation practice. They could allocate organs to kidney pancreas (KP) candidates based upon the KP match run, the kidney-alone (KI) match run, or a combination of match runs.

In the past, transplant centers could list candidates on separate or combined kidney-pancreas (KP)/pancreas-alone (PA) waiting lists. Consequently, waiting time for KP transplant varied widely across the country because of local or regional allocation decisions. Also, the previous practice did not maximize the utilization of the pancreas.

The main goals of the national Pancreas/Kidney-Pancreas Allocation System are to:

- Improve the opportunity for pancreas candidates to receive a transplant. Currently, diabetic, uremic candidates are not motivated to receive a kidney from a living donor and then wait on the list for only a pancreas because most donation service areas allocate organs to KP candidates before allocating them to PA candidates. This situation discourages candidates who need both a kidney and a pancreas to take a living donor kidney followed by a deceased donor pancreas.
- Establish a uniform, national system to govern how pancreas allografts are allocated.
- Increase utilization and reduce geographic inequities related to deceased donor pancreas allocation, access to transplantation, and the duration of a candidate's waiting time.
- Standardize the pancreas allocation process to increase access to organs and reduce waiting times for both KP and PA candidates without significantly adversely affecting access and waiting times for KI candidates, including impact on ethnicity, age, and gender.
- Develop appropriate qualifying criteria for candidates waiting for a KP transplant.
- Enhance operational efficiency, reduce computer programming requirements, and decrease OPO and OPTN administrative costs for pancreas allocation by disentangling KPs from the kidney allocation system.

Pancreatic exocrine insufficiency – the inability to properly digest food because of a lack of digestive enzymes.

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. Organ Procurement and Transplantation Network (OPTN), Policies Administrative Rules and Definitions, 06/29/2017. Available at: http://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01.
2. United Network for Organ Sharing (UNOS). Available at URL address: https://www.unos.org/.
3. U.S. Department of Health & Human Services, Organ Procurement and Transplantation Network, Kidney-Pancreas Allocation System Frequently Asked Questions. Available at: https://optn.transplant.hrsa.gov/resources/guidance/kidney-pancreas-allocation-system-frequently-asked-questions/.

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: 06/13/2007

Revision Dates: 5/18

Last Approval Date: 06/07/2018

Next Revision Date: 06/07/2019

Revision Date & Approval	Reason for Revision
August 14, 2013	Annual review and approval
August 13, 2014	Annual review and approval
July 2015	Annual review; revisions and approval. Standardized formatting. Deletions: OptumHealth as a transplant network. Additions: ICD-9 and ICD-10 codes, General Background section.
July 2016	Removed references to Medicaid/ DHHS, ICD-9 table
July 2017	Annual review w/ revisions – changed from MRM Medical Policy MP 015 to Benefit Coverage Committee Policy formatting. Added criteria for use of medical marijuana. Added Pancreas/Kidney-Pancreas Allocation System (KAS) accrual of waiting time criteria and defined under “Terms & Definitions.”
May 2018	Annual review and approval.