BENEFIT COVERAGE POLICY

Title: BCP 71 Pancreas Transplantation

Effective Date: 07/01/2022

v.5

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 pancreas transplant for members with a qualifying condition and who meet the Clinical Determination Guidelines below.

Pancreas transplant after a prior kidney transplant may be considered medically necessary in patients with insulin-dependent diabetes.

Pancreas transplant may be considered medically necessary in patient with severally disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin dependent diabetes that persists despite optimal medical management.

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

Pancreas transplantation can only be done in an inpatient setting.

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

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

2.0 Background:

Transplantation of a normal pancreas is a treatment method for patient with insulin-dependent diabetes mellitus. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications from diabetes mellitus.

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. Documentation of compliance with medical management; and
2. 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: 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).
3. 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
4. Member meets transplant institution's protocol eligibility criteria; and
5. Transplant physician has determined there are no prohibitive risks (malignancy, systemic infection, HIV infection, cardiovascular, pulmonary or hepatic).
6. Absence of any malignant neoplasm (other than non-melanomatous skin cancer) that has a significant risk of recurrence; and
7. Absence of uncontrolled HIV/AIDs infection, defined as:
    a. CD4 count greater than 200 cells/mm^3 for more than three months; and
    b. Undetectable HIV viremia (<50 HIV-1 RNA copies/ml) for at least six months; and
    c. Demonstrates adherence and a stable, highly active antiretroviral therapy regimen for at least six months; and
    d. Absence of AIDS-defining illness following successful immune reconstitution after highly active antiretroviral therapy.
9. Absence of ongoing or recurrent active infections that cannot be adequately treated; and
10. Documentation of compliance with medical management; and
11. 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

12. 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

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

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

    a. Be registered for a pancreas transplant; and

    b. Meet one of the following criteria:

        i. Is on insulin and has a fasting C-peptide value less than or equal to 2 ng/mL with a concurrently obtained fasting glucose <225 mg/dL; or

        ii. Tests positive for beta cell autoantibody.

        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.

    d. A candidate registered on the pancreas waiting list, must be diagnosed with one of the following:

        i. Diabetes that requires insulin and have complications that cannot be well managed with conventional therapy; or

        ii. Has severe pancreatic exocrine insufficiency.

15. 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.

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

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

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

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

4. Bio-artificial pancreas device (L8699).

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..

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Cost Share 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	Y	Benefits and Coverage; Transplantation Services

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Cost Share Reference**
	segment for transplantation		
48554	Transplantation of pancreatic allograft	Y	Benefits and Coverage; Transplantation Services
48556	Removal of transplanted pancreatic allograft	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
S2102	Islet cell tissue transplant from pancreas; allogeneic	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	N	Benefits and Coverage; Transplantation Services

NON-COVERED CODES		
Code	**Description**	**Benefit Plan Reference/Reason**

5.0 Unique Configuration/Prior Approval/Coverage Details:

Fully-insured SPD plan and self-funded 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.

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.

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.

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.

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

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, 04/05/2022. 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]:

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

Policies and Procedures (P&Ps) - MMP-02 Transition and 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 High Cost Notification; MMS-09 Case Management Referrals; MMS- 10 Pre-Transplant Process, MMS-11 Transplant Event and Listing, MMS-12 Post-Transplant Process, MMS-48 CCA Pre-Transplant Process, MMS-49 CCA Transplant Event and Listing, MMS-50 CCA Post-Transplant Process.

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 and LifeTrac.

9.0 Revision History:

Original Effective Date: 06/13/2007

Next Revision Date: 07/01/2023

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

Revision Date & Approval	Reason for Revision
	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; QIMRM review and approval 8/8/18.
June 2019	Annual review; added criteria for transplant evaluation eligibility, criteria r/t HIV and C-peptide updated; QI/MRM review 8/14/19.
July 2020	Annual review; criteria for HIV/AIDs transplant recipients updated, removed CPT 50380 as not applicable, PA removed for S2055 and S2152, unlisted codes 48999 and L8699 removed, approved at 7/20/20 BCC
April 2021	Annual review; removed re-transplantation criteria; removed kidney transplant criteria (now using InterQual criteria); changed policy from Pancreas-Kidney to Pancreas Transplantation; updated associated documents.
April 3 2022	Annual Revie, Removed Interlink references, updated associated documents section, S2102 changed from "NC" to "PA", effective date changed from 71/22 to 4/1/22.