MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: PA.016.MH
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

PA.016.MH – Transplant: Pancreas Alone and Pancreas/Kidney

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Pancreas and pancreas/kidney transplants** medically necessary for the following indications:

Recipient Characteristics
The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens.

General Criteria
The member meets the institution's selection criteria for pancreas or pancreas/ kidney transplantation.

Specific Criteria for Pancreas Transplant Alone (PTA)
PTA is considered medically necessary for carefully selected members who meet all of the following criteria:
1. Members must have a diagnosis of Type I Diabetes.
2. Member must be positive for autoantibodies directed against pancreatic Beta cells, which include anti-islet cell, anti-insulin, and/or anti-glutamic acid decarboxylase autoantibodies.
3. Member must be insulin dependent, adherent to treatment and refractory to intensive insulin therapy, with documented severe and/or life-threatening metabolic complications requiring urgent medical care and/or hospitalizations, including:
   - Hypoglycemia unawareness, or
   - Recurring severe hypoglycemic attacks**,** or
   - Recurring severe ketoacidosis, or
   - Recurring, severe and/or persistent hyperglycemia requiring medical attention
4. Members must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems

Specific Criteria for Simultaneous Pancreas/Kidney Transplant (SPK)

SPK is considered medically necessary for carefully selected members with end-stage renal disease from diabetic nephropathy who meets all of the following criteria:

1. End-stage renal disease requiring chronic dialysis or glomerular filtration rate less than 20 ml/min/1.73m² or less than 30 ml/min/1.73m² with uremia
2. Type 1 diabetes refractory to intensive insulin therapy as described above under the Specific Criteria for Pancreas Transplant Alone (PTA) or type 1 diabetes with one or more progressive complications of diabetes, including:
   - Diabetic retinopathy
   - Diabetic neuropathy
   - Diabetic gastroparesis
   - Arteriosclerotic vascular disease

Specific Criteria for Pancreas Transplant after Kidney Transplantation (PAK)

PAK is considered medically necessary for members with insulin dependent diabetes who meet all of the following criteria:

1. Member has undergone successful kidney transplant
2. There is absence of significant chronic rejection of the transplanted kidney
3. The transplanted kidney is stable and functioning well with a minimum creatinine clearance of 30 ml/min and the absence of significant proteinuria, and
4. All of the criteria are met for PTA or SPK

Specific Criteria for Pancreas Retransplantation

Pancreas retransplantation is considered medically necessary for selected members case by case based on treating physician's recommendations after a failed primary pancreas transplant.

Partial Pancreatic Tissue or Islet Cell Transplantation

Refer to PA-095 Pancreatectomy with Autologous Islet Cell Transplantation

Specific Criteria for Pancreas/Pancreas-Kidney Transplant in HIV+ Members

Pancreas/pancreas-kidney transplantation in HIV+ members are considered medically necessary when all of the following conditions are met:

1. The member has a life expectancy of at least five years
2. CD4 count ≥200 cells/mL for at least six months
3. Undetectable HIV viremia (<50 copies/mL) for six months
4. Demonstrated adherence to highly active antiretroviral therapy (HAART) regiment for ≥ six months
5. Available antiretroviral treatment options post-transplant.

Limitations

1. All other medical and surgical therapies that might be expected to yield both short-and long-term survival comparable to that of transplantation must have been tried or considered.
2. Members must first undergo stringent physical and psychological evaluation to determine eligibility for transplant. Members should have no other serious medical problems, and they should be psychologically willing to undergo the stressful surgery and postoperative care necessary.

Background

Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness. Members with diabetes are divided into three main categories for pancreas transplantation:

1. Members with end-stage renal failure and undergoing simultaneous kidney transplantation (SPK)
2. Members who have already had a successful kidney transplant in the past (Pancreas after kidney: PAK)
3. Members in the preuremic stage (Pancreas transplant alone: PTA).

According to the 2012 SRTR & OPTN Annual Report, the number of pancreas transplants has decreased over the past decade. Many hypothesize that this decrease can be attributed to improved insulin delivery systems and islet transplantation.

Codes:

CPT Codes	
Code	Description
48160	Pancreatectomy, total or subtotal, with transplantation of pancreas or pancreatic islet cells
48551	Backbench preparation of cadaver donor pancreas
48552	Backbench reconstruction of cadaver donor pancreas; venous anastomosis
48554	Transplantation of pancreatic allograft

1. American Diabetes Association: Living with Diabetes: Pancreas Transplantation. Last edited: November 3, 2013. http://www.diabetes.org/living-with-diabetes/treatment-and-care/transplantation/pancreas-transplantation.html

2. Becker BN, Odorico JS, Becker YT, et al. Simultaneous pancreas-kidney and pancreas transplantation. J Am Soc Nephrol. 2001; 12(11):2517-2527. http://jasn.asnjournals.org/content/12/11/2517.full.pdf+html
3. Centers for Disease Control and Prevention (CDC). HIV Basics. Last updated: Mar 3, 2017. http://www.cdc.gov/hiv/basics/index.html
4. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 260.3 - Pancreas Transplantation. Effective: 04/26/2006. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=107&ncdver=3&bc=AgAAgAAAAAAAAA%3d%3d&
5. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 260.3.1 - Islet Cell Transplantation in the Context of a Clinical Trial. Effective 10/04/2004. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&bc=AgAAgAAAAAAAAA%3d%3d&
6. CMS Manual System, Pub 100-3 Medicare National Coverage Determinations: Islet cell Transplantation in the Context of a Clinical Trial, transmittal 18, Pancreas Transplants , Chapter 1/260.3 and: Chapter 1/260.3.1. https://www.cms.gov/Transmittals/Downloads/R18NCD.PDF
7. Gruessner AC. 2011 update on pancreas transplantation: comprehensive trend analysis of 25,000 cases followed up over the course of twenty-four years at the International Pancreas Transplant Registry (IPTR). Rev Diabet Stud. 2011 Spring;8(1):6-16. doi: 10.1900/RDS.2011.8.6. Epub 2011 May 10. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3143672/pdf/RevDiabeticStud-08-006.pdf
8. Gruessner A, Sutherland DE. Pancreas transplant outcomes for United States (US) and non-US cases as reported to the United Network for Organ Sharing (UNOS) and the International Pancreas Transplant Registry (IPTR) as of June 2004. Clin Transplantation. 2005 Aug; 19(4): 433-455. http://www.ncbi.nlm.nih.gov/pubmed/19708445
9. Hariharan S, Pirsch JD, Lu CY, et al. Pancreas after kidney transplantation. J Am Soc Nephrol. 2002;13(4):1109-1118. http://jasn.asnjournals.org/content/13/4/1109.full.pdf+html
10. Humar A, Ramcharan T, Kandaswamy R, et al. Pancreas after kidney transplants. Am J Surg. 2001; 182(2):155-161. http://www.ncbi.nlm.nih.gov/pubmed/11574088
11. Kaiser Family Foundation. Global Health Reporting. AIDS 2010: The double-edged sword: Long-term complications of ART and HIV. July 19, 2010. http://kff.org/global-health-policy/event/aids-2010-the-double-edged-sword-long-term-complications-of-art-and-hiv/

12. O'Grady J, Taylor C. Guidelines for liver transplantation in patients with HIV infection (2005). HIV Med. 2005 Jul;6 Suppl 2:149-153. [British HIV Association]. http://onlinelibrary.wiley.com/doi/10.1111/j.1468-1293.2005.00303.x/pdf
13. Robertson RP. Pancreas and islet transplantation in diabetes mellitus. UpToDate. Topic 1767. Version 11.0. Last Updated: Feb 13, 2018. http://www.uptodate.com/contents/pancreas-and-islet-transplantation-in-diabetes-mellitus?source=search_result&search=Pancreas+and+islet+transplantation&selectedTitle=1%7E150
14. Robertson RP. Patient selection for and immunologic issues relating to kidney-pancreas transplantation in diabetes mellitus. UpToDate. Topic 7305 Version 8.0. Last Updated: Feb 21, 2019. http://www.uptodate.com/contents/patient-selection-for-and-immunologic-issues-relating-to-kidney-pancreas-transplantation-in-diabetes-mellitus?source=search_result&search=Pancreas+and+islet+transplantation&selectedTitle=3%7E150
15. Robertson RP, Davis C, Larsen J, et al. Pancreas and islet transplantation for patients with diabetes mellitus (Technical Review). Diabetes Care. 2000; 23:112-116. http://care.diabetesjournals.org/content/23/1/112.full.pdf
16. SRTR & OPTN Annual Data Report 2012 – Pancreas. http://srtr.transplant.hrsa.gov/annual_reports/2012/pdf/02_pancreas_13.pdf
17. Sutherland DE, Gruessner RW, Gruessner AC. Pancreas transplantation for treatment of diabetes mellitus. World J Surg. 2001:25:487-496. https://pubmed.ncbi.nlm.nih.gov/11344403/
18. Thompson MA, Aberg JA, Hoy JF, et al. Antiretroviral treatment of adult HIV infection: 2012 recommendations of the International Antiviral Society-USA panel. JAMA. 2012 Jul 25;308(4):387-402. doi: 10.1001/jama.2012.7961. http://jama.jamanetwork.com/article.aspx?articleid=1221704

Archived References

1. Hayes. Medical Technology Directory. Pancreas Transplantation Alone (PTA). Publication Date : February 27, 2006. Annual Review : March 19, 2010. Archived: March 27, 2011.

Disclaimer:

Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.