

PA.016.MPC Transplant: Pancreas and Autologous Islet Cell

Maryland Physicians Care considers **Pancreas and Autologous Islet Cell** medically necessary as indicated below.

Indications for Pancreas and Pancreas/Kidney Transplants ^(1,2)

Specific Criteria for Pancreas Transplant Alone (PTA)

PTA is considered medically necessary for carefully selected members with 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 that meet all of the following criteria:

1. Members must have a diagnosis of Type I Diabetes.
2. 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
5. Members must have intact, stable kidney function

Specific Criteria for Simultaneous Pancreas/Kidney Transplant (SPK)

SPK is considered medically necessary for members that meet the criteria above for pancreas transplant, as well as:

1. End-stage renal disease from diabetic nephropathy, requiring chronic dialysis or glomerular filtration rate less than 30 ml/min/1.73m²

Specific Criteria for Pancreas Transplant after Kidney Transplantation (PAK)

PAK is considered medically necessary for members that meet the criteria above for pancreas transplant, when all of the following criteria are met:

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

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Specific Criteria for Pancreas Retransplantation

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

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 ⁽³⁾:

1. The member has a life expectancy of at least five years
2. CD4 count ≥ 200 cells/mL for at least three months prior to transplant
3. Undetectable HIV viremia (< 50 copies/mL)
4. Demonstrated adherence to highly active antiretroviral therapy (HAART) regimen
5. Absence of active opportunistic infection(s) and malignancies
6. Absence of chronic wasting or severe malnutrition
7. Available antiretroviral treatment options post-transplant.

Limitations for Pancreas and Pancreas/Kidney Transplants

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.

Indications for Total Pancreatectomy with Autologous Islet Cell Transplantation

Evolent considers Pancreatectomy with Autologous Islet Cell Transplantation (TPAIT) medically necessary for the following indications:

1. Chronic pancreatitis with intractable pain, when previous conservative, endoscopic, or surgical treatments were ineffective
2. Acute relapsing pancreatitis (ARP) with episodes that are frequent, disruptive and persist over time, when previous conservative, endoscopic, or surgical treatments were ineffective
3. Other benign disease(s) of the pancreas including:
 - a. Hereditary/genetic pancreatitis
 - b. Severe pancreatic fistulas
 - c. Cystic fibrosis
 - d. Cystic neoplasms
 - e. Insulinomas

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f. Pancreatic and other neuroendocrine tumors

Limitations for TPAIT

Islet Cell extraction for Auto-transplantation can be performed only in facilities that are Food and Drug Administration (FDA) approved for extraction of Islet cells from the Pancreas. Accordingly, the following procedures are considered experimental and/or investigational and are therefore not covered for chronic pancreatitis:

- Xenogeneic Islet Cell Transplant (all xenogeneic transplants are considered experimental and investigational)
- All other indications not listed in this policy.

Contraindications for TPAIT

Total Pancreatectomy with Autologous Islet Cell Transplant is contraindicated in patients with ⁽⁴⁾:

1. C-peptide negative diabetes
2. Type 1 diabetes
3. Portal vein thrombosis
4. Portal hypertension
5. Advanced liver or cardiopulmonary disease
6. Pancreatic cancer
7. Psychosocial contraindications for TPAIT such as active alcohol abuse, active illicit substance use, and untreated/uncontrolled psychiatric disease that could impair the patient's ability to adhere to complicated medical management

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 pre-uremic 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.

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Chronic pancreatitis is the inflammation of the pancreas that worsens with time ultimately leading to the destruction of the gland. It can lead to exocrine pancreatic insufficiency and diabetes. Treatment options include pain management and dietary modifications initially, but chronic and recurrent episodes may lead to an autologous islet cell transplantation.

Autologous islet cell transplantation is an alternative for persons undergoing total pancreatectomy for severe, refractory chronic pancreatitis. Near total or total pancreatic resection can alleviate pain in patients with severe pancreatitis. Autologous islet cell transplantation can preserve islet cell function in patients undergoing this procedure. In autologous islet transplantation during the pancreatectomy procedure, islet cells are isolated from the resected pancreas using enzymes, and a suspension of the cells is injected into the portal vein of the patient's liver. Once implanted, the beta cells in these islets begin to make and release insulin.

One of the goals of pancreatectomy with autologous islet cell transplantation is to prevent the onset of diabetes, reduce the severity of the disease, reduce the pain and ultimately improve one's quality of life.

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
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

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3. Blumberg EA, Rogers CC. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. 2019;33(9). doi:10.1111/ctr.13499.
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4. Jabłońska B, Mrowiec S. Total Pancreatectomy with Autologous Islet Cell Transplantation—The Current Indications. *J Clin Med*. 2021;10(12):2723. doi:10.3390/jcm10122723
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