Clinical Coverage Guidelines – Pancreas Alone, Pancreas-Kidney Transplant and Pancreas Islet Transplantation

Effective Date: 01/01/12
Policy Number: OCA: 3.25
Product Applicability:
- MassHealth
- Commonwealth Care
- Commercial

Summary: The Plan considers pancreas and pancreas-kidney transplantation medically necessary as an alternative to continued insulin therapy in diabetic patients based upon clinical criteria. Pancreatic islet transplantation holds significant promise, however at this time islet transplantation is in clinical trials and considered an experimental and investigational procedure.

Description of Item or Service:

Pancreas Transplantation: A pancreas transplant alone (PTA), simultaneous pancreas kidney (SPK), pancreas after kidney (PAK) and simultaneous cadaver-donor pancreas and living donor kidney (SPLK) procedures involve implanting healthy organs into the recipient from a deceased or living donor, (whole pancreas, segmental pancreas segment or pancreas/kidney). Typically, the recipient’s pancreas is not removed.

- **PAK:** The planned surgical removal of a deceased donor pancreas for implantation into a recipient following a successful kidney transplant in the same recipient. Frequently PAK is done using a living donor kidney
- **PTA:** The surgical removal of a deceased donor pancreas alone for implantation into a recipient
- **SPK:** The concurrent surgical removal of a pancreas and kidney from the same deceased donor and the implantation of the pancreas and kidney into a recipient patient
- **SPLK:** The concurrent surgical removal of a deceased donor pancreas and a living-donor kidney for implantation into a recipient in one surgical procedure

Clinical Guideline Statement: Pancreas transplantation procedures require prior authorization by the Plan and may be considered medically necessary when the following criteria are met:

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The Plan considers pancreas and pancreas-kidney transplantation medically necessary when the transplanting institution eligibility criteria and all of the following are met:

1. As an alternative to continued insulin therapy in type 1 diabetic patients who meet all of the following criteria:
   - A history of frequent, acute and severe metabolic complications (hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention
   - Clinical and emotional problems with exogenous insulin therapy that are incapacitating
   - Consistent failure of insulin based management to prevent complications

2. In type 2 diabetic patients who meet all of the following criteria:
   - A history of secondary complications of diabetes
   - Are in need of a kidney transplant
   - Have been cleared for transplant by a multidisciplinary committee

The following specific criteria must be followed for each individual type of pancreas transplantation that include but are not limited to:

- **SPK and SPLK**: Indicated for patients with severe, uncontrolled type 1 diabetes and end stage renal disease documented by creatinine clearance below 30 mL/min where the risks of transplantation and chronic immunosuppression are less than the risk of continued diabetic complications.
- **PAK**: Indicated for patients with severe, uncontrolled type 1 diabetes that have had a successful kidney transplant documented by adequate renal function documented by creatinine clearance above 60mL/min. These patients must not have excessive surgical risk for the dual transplant procedure.
- **PTA**: Indicated for patients with severe, uncontrolled type 1 diabetes in the absence of end stage renal disease documented by creatinine clearance above 60mL/min.

Additional Definitions:

**End Stage Renal Disease (ESRD)**: Chronic irreversible renal failure resulting in the kidneys inability to excrete wastes, concentrate urine and regulate electrolytes. Complications are multiple and severe and without dialysis or kidney transplantation, death will likely occur.

**Kidney**: A bean shaped organ that removes waste products of metabolism from the blood and excretes them in urine, one of a pair of organs located on each side of the abdominal cavity.
**Pancreas:** A tongue shaped glandular organ that is located below and behind the stomach that secretes insulin and glucagons for the regulation of blood sugar and digestive enzymes.

**Segmental Pancreas:** A portion or segment of the pancreas

**Type 1 Diabetes Mellitus:** Also known as insulin dependent diabetes mellitus (IDDM) or juvenile diabetes, this type of diabetes is characterized by a severe deficiency of insulin secretion that usually develops during childhood or adolescence resulting in atrophy of the islets of Langerhans in the pancreas and causes hyperglycemia and a tendency towards ketoacidosis.

**Uremia:** The accumulation of constituents in the blood that are normally eliminated in the urine producing a severe toxic condition that usually occurs in end stage renal disease.

**Applicable Coding:** Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>48550</td>
<td>Donor pancreatectomy, with or without duodenal segment for transplantation</td>
</tr>
<tr>
<td>48551</td>
<td>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 arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery</td>
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<tr>
<td>48552</td>
<td>Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each</td>
</tr>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
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<tr>
<td>48556</td>
<td>Removal of transplanted pancreatic allograft</td>
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<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>G0341</td>
<td>Percutaneous islet cell transplant, includes portal vein catheterization and infusion</td>
</tr>
<tr>
<td>G0342</td>
<td>Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion</td>
</tr>
<tr>
<td>G0343</td>
<td>Laparotomy for islet cell transplant, includes portal vein catheterization and infusion</td>
</tr>
<tr>
<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
</tr>
<tr>
<td>S2102</td>
<td>Islet cell tissue transplant from pancreas; allogeneic</td>
</tr>
</tbody>
</table>
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0141T Pancreatic islet cell transplantation through portal vein, percutaneous
0142T Pancreatic islet cell transplantation through portal vein, open
0143T Laparoscopy, surgical, pancreatic islet cell transplantation through portal vein

**Limitations:**
Pancreatic islet transplantation holds significant promise, however at this time islet transplantation is in clinical trials and considered an experimental and investigational procedure.

**Clinical Background Information:**
Pancreas transplantation is intended to restore normal insulin secretion in patients with Diabetes Mellitus and is the most proven therapy that restores continuous euglycemic control, slows the progression of end-organ complications and improves quality of life in type I diabetics. There are three types of kidney/pancreas transplants: simultaneous pancreas kidney (SPK), pancreas transplant alone (PTA) and pancreas after kidney (PAK). SPK is typically offered to patients who have insulin-dependent diabetes mellitus and in whom diabetic nephropathy and renal insufficiency have developed. Many of these patients have other complications of diabetes including retinopathy, neuropathy and gastropathy. In most SPK transplants, both organs are from the same cadaver donor but it is possible to use a living donor for a segmental pancreas transplant and a cadaver kidney. Additionally, it is possible to do a living donor kidney transplant simultaneously with a cadaver donor pancreas (SPLK). PTA is generally done for patients who have severe, uncontrolled diabetics without renal failure who have failed insulin based management and may have incapacitating clinical or emotional problems with insulin therapy. PAK is generally the option for patients who have a living donor for the kidney. The timing of transplant is different for each. With SPK, both organs are transplanted at the same time and with PAK, the pancreas is transplanted as a planned separate procedure that is usually done several months following a successful kidney transplant. For pancreas transplantation alone (PTA), life long immunosuppression is required to prevent rejection of the graft and potential recurrence of the autoimmune process that might destroy pancreatic islet cells again. Pancreas transplants are typically not performed in children under the age of 18 but may be done as part of a multivisceral transplant involving other organs such as liver, pancreas, stomach and/or kidney.

Many factors can affect the outcome of transplant procedures. Fairly rigid selection criteria are required to obtain optimal results for each patient. Contraindications for pancreas kidney and pancreas transplantation include but are not limited to:

1. **Absolute Contraindications:**
   - Advanced peripheral vascular disease not amenable to surgical therapy
   - Uncorrectable coronary artery disease
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2. Relative Contraindications:
   - Advanced autonomic neuropathy
   - Morbid obesity (BMI >35)
   - Active substance abuse within the last 6 months including tobacco, alcohol and narcotics or other addictive pain medications
   - Age < 18 years or > 65 years
   - Cerebrovascular accident (CVA) that is not amenable to rehabilitation
   - Recent retinal hemorrhage
   - History of malignancy treated within the last 3 years (excluding non-melanoma skin cancer)

Candidates for pancreas transplantation must undergo a thorough pre-transplant evaluation by a multidisciplinary team comprised of surgeons, transplant coordinators, social workers, nutritionist, pharmacist and other specialists as indicated. Typically, the pre-transplant work-up includes:

- Blood work: CBC with differential count, sedimentation rate, electrolytes, pancreatic enzymes: lipase & amylase, lipid profile, liver function tests, coagulation profile and serology’s
- Cardiovascular: 12 lead ECG, chest x-ray, echocardiogram, carotid artery ultrasound, exercise treadmill test, vascular Doppler studies
- Renal: Urinalysis, 24 hour creatinine clearance, glomerular filtration rate, urine microalbumin and total protein
- Endocrine: Cortisol level, thyroid studies and bone density testing
Postoperative care of the transplant recipient includes monitoring and management that focuses on the prevention of infection, thrombosis, and graft rejection. Patients are given antibiotics, anti-coagulation and immunosuppression therapy following the surgery. Surgical complications can include: graft thrombosis, infection, anastomotic leak, pancreatitis and bleeding. Rejection of the transplant can occur at any time following the transplant.

**References:**


Drognitz O et al. Long-Term Follow-Up of 78 Simultaneous Pancreas-Kidney Transplants at a Single-Center Institution in Europe. Transplantation 2004 Dec;78(12):1802-1808


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 Registry (IPTR). Rev Diabet Stud 2011 Spring;8(1):6-16. Epub 2011 May 10

Gruessner AC et al. Pancreas transplant outcomes for United States (US) cases as reported to the United Network for Organ Sharing (UNOS) and the International Pancreas Transplant Registry (IPTR). Clin Transpl. 2008;45-56


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Next Review Date
09/01/12

Approval Dates
Regulatory Approval: N/A
Internal Approval:
08/01/06: Initial approval Q&CMC
07/11/07: MPCTAC
07/24/07: UMC
08/13/07: QIC
09/09/08: MPCTAC
09/30/08: UMC
10/22/08: QIC
08/25/09: MPCTAC & UMC
09/23/09: QIC
09/15/10: MPCTAC
10/27/10: QIC
09/21/11: MPCTAC
10/26/11: QIC

Authorizing Entity
QIC

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses the Plan’s determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. The Plan has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered or not covered, this conclusion is not based upon the terms of a member’s particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all services that are determined to be medically necessary will necessarily be covered services under the terms of a member’s benefit plan. Members and their providers need to consult the applicable benefit plan document (e.g., Evidence of Coverage) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this medical policy and the benefit plan document, the provisions of the benefit plan document will govern. In addition, this policy and the benefit plan document are subject to applicable state and federal laws that may mandate coverage for certain services and supplies.