Kidney Transplantation, Pancreas-Kidney Transplantation, and Pancreas Transplantation Alone

Table of Contents

Coverage Policy .................................................. 1
Overview.............................................................. 3
General Background ........................................... 3
Coding/Billing Information .................................... 6
References .......................................................... 9

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Note: Selected candidates may be eligible for multi-organ transplantation. In each case, the candidate should meet all of the criteria for selection for the individual transplant being considered.

Kidney Transplantation

Kidney transplantation is considered medically necessary when ANY of the following criteria are met:

- adults (i.e., >18 years of age) measured or calculated creatinine clearance or glomerular filtration rate (GFR) less than or equal to 20 mL/min/1.73m².
- pediatric (i.e., ≤18 years of age) stage 4 chronic kidney disease (estimated GFR <30 mL/min per 1.73m²)
- end-stage renal disease (ESRD) on regularly administered dialysis

Simultaneous Pancreas-Kidney (SPK) Transplantation
Simultaneous pancreas-kidney (SPK) transplantation is considered medically necessary when the following criteria are met:

- medical necessity for kidney transplantation is met, and
- EITHER of the following indications:
  - diabetes mellitus
  - pancreatic exocrine insufficiency with renal insufficiency

AND ONE of the following qualifying criteria:

- individual >18 years of age with EITHER of the following:
  - on insulin and C-peptide less than or equal to 2 ng/mL
  - on insulin and C-peptide greater than 2 ng/mL and has a body mass index (BMI) ≤ 28 kg/m²
- individual ≤ 18 years of age must be registered on the UNOS waiting list but does not have to meet qualifying criteria

**Pancreas Transplantation Alone (PTA)**

Pancreas transplantation alone (PTA) is considered medically necessary for an individual with diabetes mellitus, which despite maximal medical management and adherence to treatment recommendations, is poorly controlled as manifested by the presence of BOTH of the following:

- history of frequent, acute and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) of such severity that requires medical attention
- failure of insulin-based management to prevent acute complications

**Pancreas-After-Kidney (PAK) Transplantation**

Pancreas-after-kidney transplantation (PAK) is considered medically necessary when the following criteria are met:

- medical necessity for pancreas transplantation alone (PTA) is met, and
- individual with diabetes mellitus

**Not Covered**

Kidney, pancreas, or pancreas-kidney transplantation for an individual with ANY of the following contraindications to transplant surgery is considered not medically necessary:

- malignancy that is expected to significantly limit future survival
- persistent, recurrent or unsuccessfully treated major or systemic extra-renal infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
- a pattern of demonstrated patient noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless ALL of the following are noted:
  - CD4 count greater than 200 cells/mm³
  - HIV-1 ribonucleic acid (RNA) undetectable
  - Stable anti-retroviral therapy for more than three months
  - Absence of serious complications associated with HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, or resistant fungal infections; or Kaposi’s sarcoma or other neoplasm)

The following are considered experimental, investigational or unproven:
• living donor pancreas transplantation (i.e., partial pancreas transplantation, segmental pancreas transplantation)
• bioartificial pancreas device

Overview

This Coverage Policy addresses kidney transplantation, pancreas-kidney transplantation, and pancreas transplantation alone.

General Background

Kidney Transplantation

End-stage renal disease (ESRD) occurs when the kidneys are no longer able to function at a level that is necessary for day-to-day life. ESRD almost always follows chronic kidney failure, which may exist for 10–20 years or more before progression to ESRD. Glomerular filtration rate (GFR) is considered the best measure of kidney function. While the lower limit of normal GFR varies with age, a GFR level below 60 mL per minute per 1.73m² represents loss of one half or more of the adult level of normal kidney function. A GFR of <30 mL/min/1.73 m² is considered to be abnormal in all ages other than neonates.

Kidney failure, (i.e., chronic kidney disease [CKD] stage 5) is defined as either a GFR below 15 mL per minute per 1.73 m² which, in most cases is accompanied by signs and symptoms of uremia, or a need to start kidney replacement therapy (i.e., dialysis or transplantation) for the treatment of complications of decreased GFR (Johnson, et al. 2004; Levey, et al. 2003). Patients with advanced CKD (Kidney Disease Outcomes Quality Initiative [K/DOQI™] CKD Stages 4 and 5) have a high propensity for progression to ESRD in a relatively short period of time with well-known multiple comorbid conditions and poor outcomes.

Kidney transplantation is the grafting of a kidney from either a living or deceased (i.e., cadaver) donor. Both pediatric and adult kidney transplant recipients have increased survival compared to patients who remain on dialysis. Kidney transplantation should be timed to occur as close as possible to when the recipient would be expected to require dialysis; however, transplantation should be delayed in patients who may regain kidney function (e.g., malignant hypertension, severe, acute tubular necrosis). Transplantation performed prior to the need for dialysis is called preemptive transplantation. It confers a survival advantage to the recipient and is more common for recipients of living-donor kidneys. Preemptive kidney transplant has been shown to provide better outcomes compared to transplant after any period of time on dialysis; however, because of the shortage of donors, preemptive transplantation may not be possible. Kidney transplantation is an accepted and successful treatment for many individuals with ESRD. The transplant evaluation should begin when it is clear that the patient is destined to develop ESRD. In the event of subsequent renal graft failure, retransplantation is often performed.

The United Network for Organ Sharing (UNOS)/Organ Procurement Transplant Network (OPTN, 2018) have established organ allocation registration and waiting time criteria for kidney transplantation depending on the age of the transplant candidate. Adults (i.e., individuals >18 years) may be listed if the measured or calculated creatinine clearance or glomerular filtration rate (GFR) is less than or equal to 20 mL/min or have end-stage renal disease (ESRD) on regularly administered dialysis. An individual ≤18 years of age may be listed if they have ESRD and are on regularly administered dialysis, regardless of clinical criteria for creatinine clearance or GFR. Dialysis is generally considered in an individual with ESRD stages 4 or greater.

An integral part of the nation’s organ donation system is the living donor. Living donors can be related or unrelated to the recipient. Living kidney donation eliminates the recipient’s need for waiting time on a national waiting list, are often more successful, and can add psychological benefits to both donor and recipient. Nonetheless, the benefit to the recipient of a live-donor organ must outweigh the risks to the donor. In the absence of a living donor, many transplanted kidneys come from deceased (i.e., cadaver) organ donors.
Retransplantation: In general, retransplantation is considered by some to be a controversial procedure, in part due to ethical concerns over the limited supply of organs. A wide range of donor, recipient and other transplant-related factors can influence graft survival. In the event of renal graft failure, renal replacement therapy consists of either dialysis or retransplantation. Although allograft survival is considered good, it is considerably less compared to the primary transplant. Candidates awaiting kidney retransplant are often allosensitized and may be less likely to receive a transplant than primary candidates. As a result, some transplant centers have developed ongoing efforts involving desensitization protocols to prevent antibody-mediated acute rejection. Although desensitization protocols may be considered for deceased donor kidney, protocols are generally attempted with living donation so that antibody response against donor tissue can be monitored; patients proceed to transplant surgery only if antibody levels are low. Authors contend that desensitizing highly sensitive patients improves clinical outcomes (short-term patient and graft survival) however acute antibody-mediated rejection is a barrier in 20-30% of patients and there is no consensus regarding which protocol is ideal.

Pancreas Transplantation

The standard treatment for control of blood sugar levels in type I diabetes mellitus (DM) is the use of exogenous insulin; however, this does not entirely restore normal glucose metabolism. Most people who are newly diagnosed with type 2 diabetes are usually treated with a combination of diet, exercise, and an oral medication. Some oral medications (e.g., metformin) improve the body's response to insulin. Other medications cause the body to produce more insulin. Some people will need to add insulin or another injectable medication because their blood sugar levels are not controlled. Using a combination of treatments (oral medication plus insulin) generally means that the person can take a lower dose of insulin, compared with if insulin treatment is used alone.

Pancreas transplantation has been demonstrated to improve the quality of life of people with diabetes, primarily by eliminating acute complications. Pancreas transplantation eliminates the need for exogenous insulin, daily glucose monitoring and many dietary restrictions imposed by diabetes. Additional benefits of pancreas transplantation include the elimination of life-threatening risks of hypoglycemic unawareness and prevention and reversal of diabetic nephropathy. Pancreas transplantation may be performed:

- alone (i.e., Pancreas Transplantation Alone [PTA]), or
- simultaneously with kidney transplants (i.e., Simultaneous Pancreas-Kidney [SPK]) or
- after a kidney transplant (i.e., Pancreas After Kidney [PAK])

OPTN (2018) specifies that for PTA, the candidate must be diagnosed with diabetes or have pancreatic exocrine insufficiency. Each candidate registered on the pancreas-kidney (SPK) waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency, with renal insufficiency. OPTN qualifying allocation criteria for SPK recipients >18 years include: must be on insulin and have a C-peptide ≤2ng/mL; or, on insulin, have a C-peptide ≥2ng/mL and have a body mass index (BMI) less than or equal to the maximum allowable BMI (28 kg/m²). An individual ≤18 years does not have to meet these additional qualifying criteria.

Evidence in the scientific published literature supports pancreas transplantation as an appropriate therapeutic intervention for individuals with diabetes or who have pancreatic exocrine insufficiency who require or have previously had a kidney transplant. Pancreas transplantation is a well-established and accepted method of treatment for these individuals, particularly the type 1 diabetic. More recently, pancreas transplant has become an accepted method of treatment for type 2 diabetics, with both short-term and long-term outcomes commensurate with type 1 diabetes patients (Gruessner, et al., 2017; Redfield, et al., 2015; Weems, et al., 2014; Margreiter, et al., 2013, Light, et al., 2013; Wiseman, et al., 2012; Sampaio, et al., 2011; Chakkera, et al., 2010; Light, et al., 2005; Nath, et al., 2005). Gruessner et al. (2017) reported patient, pancreas, and kidney graft survival rates increased significantly over time and reached 95.8, 83.3, and 91.1%, respectively, at 3 years post-transplant for transplants performed between 2009 and 2015.

Living Donor Pancreas Transplantation: Both the American Diabetes Association and UNOS recognize and provide information regarding living donor pancreas transplantation. Living donor pancreas transplantation has been performed in a few centers, including those outside the United States; however it is not considered widespread in clinical practice. In many cases, the living pancreas donor is a relative of the recipient. In the United States living donor pancreas transplantation has been largely studied at one center, the University of
Between January 1, 1994 to May 1, 2013, a total of 46 living-donor segmental pancreas transplants (LDSPTx) including 40 SPK, 2 PAK, and 4 PA were performed at the University of Minnesota (Kirchner, et al., 2016). Kirchner et al. stated that the rate of LDSPTx has significantly decreased over the last few years (on intent) in order to assess donor outcomes and safety prior to actively continuing the living donor (LD) pancreas program. The new onset of diabetes mellitus (DM) requiring oral hypoglycemic management was diagnosed in 7 (15%) donors and insulin-dependent DM in 5 (11%). LD pancreas transplantation (especially SPK) should be offered in carefully selected donor-recipient pairs if metabolic risks for the donor are minimized by careful pre-donation screening and meticulous post-donation follow-up with interventions to prevent significant weight gain. Kirchner et al. concluded that LDSPTx can be performed with good recipient outcomes. The donation is associated with donor morbidity including impaired glucose control. Donor morbidity can be minimized by using risk stratification model and pre-donation counseling on life style modifications post-donation (Kirchner, et al., 2016).

The evidence for living donor pancreas transplantation is limited and primarily in the form of few retrospective reports and patient-registry data Kirchner, et al., 2016; Choi, et al., 2016; Otsuki, et al., 2014; Matsumoto, et al., 2014; Sutherland, et al., 2012). Donor and recipient selection criteria for living donor pancreas transplantation have not been clearly defined in the medical literature. Long-term clinical outcomes for the donor and recipient have not been reported. In the short-term, there is limited evidence supporting normalizing insulin production for selected recipients but concerns remain regarding negative metabolic impact to donors.

Note: For islet cell transplantation, see Coverage Policy 0107 Pancreatic Islet Cell Transplantation.

Retransplantation: For all three types of pancreas transplants, survival rates for a second transplant are lower than for the primary transplant, although an elective retransplant may be considered suitable for a select group of patients. The medical literature suggests in some patients, a retransplant could improve health outcomes after graft loss, although there is insufficient data regarding health outcomes associated with third and subsequent pancreas transplants to allow strong conclusions.

Contraindications to Kidney Transplantation, Pancreas-Kidney Transplantation, and Pancreas Transplant Alone

Many factors affect the outcome of a solid organ transplant. A fairly rigid selection process is required in order to obtain the best result for each patient. In addition to the absolute contraindications noted in the Coverage Position above, relative contraindications to pancreas or pancreas-kidney transplantation include, but are not limited to, the following (Becker, 2012; Bunnapradist, 2007; Knoll, 2005; Hillerman, 2002; Danovitch, 2001; Kaisiske, 2001; Steinman, 2001):

- active substance abuse within the last six months, including tobacco, alcohol and narcotic/other addictive pain medications
- potential complications from immunosuppressive medications that are unacceptable to the patient
- cerebrovascular disease or accident or progressive neuropathy or myopathy that is not amenable to rehabilitation
- body mass index (BMI) less than 17 or greater than 33
- any active medical process that is currently not optimally treated and/or stable and that is likely to result in end-organ damage or medical emergency without appropriate management, such as active peptic ulcer disease, diverticular disease, active hepatitis, cholecystitis, pancreatitis, hypertension, autoimmune disease or cytopenia
- untreated osteoporosis with a T-score greater than 2.5 standard deviations (SD) from mean or Z-score greater than two SD from mean
- hepatic fibrosis or cirrhosis
- hepatitis C with biopsy-proven, histologic evidence of hepatic disease
- uncorrected abdominal aortic aneurysm greater than four centimeters
- advanced age
- peripheral vascular disease not amenable to surgical or percutaneous therapy as evidenced by:
  - asymptomatic stenosis greater than 75% or symptomatic carotid stenosis of less severity
  - ankle brachial index less than 0.7 or substantial risk of limb loss with diminished perfusion
• systemic infection making immune response risky, including human immunodeficiency virus (HIV), hepatitis B virus (HBV) in the recipient or cytomegalovirus (CMV) in the donor

Additionally, there are other conditions that may affect the outcome of kidney transplantation, pancreas-kidney transplantation and pancreas alone transplantation and require further investigation to ensure the best chance for successful transplantation:

• history of recurrent infection or bladder dysfunction indicates the need for a urological evaluation
• potential for renal malignancy should be screened by use of magnetic resonance imaging (MRI), computed tomography (CT) or renal ultrasound
• reflux nephropathy, history of recurrent infections, nephrolithiasis, heavy proteinuria, hypertension resistant to therapy, or enlarged or symptomatic polycystic kidneys should be evaluated for potential nephrectomy

For pancreas-kidney transplantation further investigation for the following should occur to ensure the best chance for successful pancreas-kidney transplantation:

• autosomal dominant polycystic kidney disease (ADPKD): high-resolution CT or MRI to evaluate for intracranial aneurysms

Bioartificial Pancreas
Bioartificial pancreas devices are currently being investigated by some authors. In theory, the technology involves transplanting healthy islet cells (pancreatic cells that release insulin) into a subject with diabetes; current studies consist mainly of animal trials. Islet cell sources include human or allogeneic cells, porcine or xenograftic cells, and engineered cells. The islet cells are encapsulated with a semipermeable membrane, such as hydrogel or polymer, and are then placed in the body. Authors contend the bioartificial pancreas device acts as a substitute for the endocrine portion of the pancreas, avoiding obstacles in islet cell transplantation which include limited supply and immunosuppressive drug therapy. The optimal site for implantation has not been clearly defined, although the intended use is for implantation into a vascular site or the peritoneal cavity.

Professional Societies/Organizations
In 1984 the National Organ Transplantation Act directed the Secretary of HHS to ‘establish by contract the Organ Procurement and Transplantation Network (OPTN) which shall be a private, non-profit entity that has an expertise in organ procurement and transplantation’. The United Network for Organ Sharing (UNOS) is the current OPTN Contractor. OPTN policies are updated annually and are rules that govern operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S. Policies are made through a collaborative process involving committees, the board of directors and the public.

Kidney Disease: Improving Global Outcomes (KDIGO) published guidelines focus on topics related to the prevention or management of individuals with kidney diseases. Related guidelines include Care of Kidney Transplant Recipients (Kasiske, et al., 2009) and KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease (KDIGO, 2013).

The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative (2017): No relevant information found.

Use Outside of the US: The NHS Organ Donor Register is the equivalent to the US’ UNOS. In Japan, an Organ Transplant Law took effect in October 1997 and the Japan Organ Transplant Network (JOTNW) was established to deal with heart and liver transplants in addition to kidneys. The Canadian Organ Replacement Register (CORR) is a pan-Canadian information system and is responsible for maintaining a list of contact information for dialysis, transplant and organ procurement centers across Canada as well as producing in-depth reports and analyses on long-term trends on organ transplants. The Australia and New Zealand Organ Donation (ANZOD) Registry records and reports on organ donation within Australia and New Zealand.
Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Kidney Transplantation**

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>50300</td>
<td>Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral</td>
</tr>
<tr>
<td>50320</td>
<td>Donor nephrectomy (including cold preservation); open, from living donor</td>
</tr>
<tr>
<td>50323</td>
<td>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</td>
</tr>
<tr>
<td>50325</td>
<td>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 necessary</td>
</tr>
<tr>
<td>50327</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>50328</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each</td>
</tr>
<tr>
<td>50329</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each</td>
</tr>
<tr>
<td>50340</td>
<td>Recipient nephrectomy (separate procedure)</td>
</tr>
<tr>
<td>50360</td>
<td>Renal allotransplantation, implantation of graft; without recipient nephrectomy</td>
</tr>
<tr>
<td>50365</td>
<td>Renal allotransplantation, implantation of graft; with recipient nephrectomy</td>
</tr>
<tr>
<td>50370</td>
<td>Removal of transplanted renal allograft</td>
</tr>
<tr>
<td>50547</td>
<td>Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor</td>
</tr>
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<table>
<thead>
<tr>
<th>HCPCS Codes</th>
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<tbody>
<tr>
<td>S2152</td>
<td>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</td>
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**Simultaneous Pancreas-Kidney Transplantation**

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<tbody>
<tr>
<td>48550</td>
<td>Donor pancreatectomy (including cold preservation), 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>
</tr>
<tr>
<td>48552</td>
<td>Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each</td>
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<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>48556</td>
<td>Removal of transplanted pancreatic allograft</td>
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<td>50300</td>
<td>Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral</td>
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<td>50320</td>
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<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
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<tr>
<td>S2152</td>
<td>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</td>
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**Pancreas-After-Kidney Transplantation**

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Pancreas Transplantation Alone

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Considered Experimental/Investigational/Unproven when used to report living donor pancreas transplantation (i.e., partial pancreas transplantation, segmental pancreas transplantation):

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<th>CPT® Codes</th>
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<tbody>
<tr>
<td>48999</td>
<td>Unlisted procedure, pancreas</td>
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Considered Experimental/Investigational/Unproven when used to report bioartificial pancreas device:

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<th>HCPCS Codes</th>
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<tbody>
<tr>
<td>L8699</td>
<td>Prosthetic implant, not otherwise specified</td>
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References


