MEDICAL POLICY

Excellus
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Medical Policy Title	**Pancreas Transplant: (Pancreas Transplant Alone, Pancreas Transplant after Kidney Transplant, Simultaneous Pancreas Kidney Transplant): Islet Cell Transplant**
Policy Number	**07.02.01**
Current Effective Date	March 20, 2025
Next Review Date	March 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Pancreatic Transplant Alone (PTA)

I. Pancreas transplant alone (PTA) procedure is considered **medically appropriate** in a carefully selected subset of individuals when **ALL** the following criteria are met:

   A. who have insulin dependent diabetes mellitus (IDDM) that is difficult to manage (e.g., labile);

   B. a history of frequent, acute, and severe metabolic complications (hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention;

   C. consistent failure of insulin-based management to prevent acute complications; **and**

   D. do not have advanced kidney disease (stage IV or V chronic kidney disease (CKD)).

Pancreas After Kidney Transplant (PAK)

II. Pancreas transplant after kidney transplant (PAK) is considered **medically appropriate** for individuals who have IDDM when **ALL** the following criteria are met:

   A. who have had a previous successful kidney transplantation for uremia or kidney failure;

   B. a history of frequent, acute, and severe metabolic complications (hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention;

   C. consistent failure of insulin-based management to prevent acute complications; **and**

   D. does not have advanced kidney disease (stage IV or stage V CKD).

Simultaneous Pancreas-Kidney Transplantation (SPK)

III. Simultaneous transplant of the pancreas is considered **medically appropriate** when **ALL** the following criteria are met:

   A. for uremic IDDM individuals who have no immediate life-threatening conditions;

   B. a history of frequent, acute, and severe metabolic complications (hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention; **and**

   C. consistent failure of insulin-based management to prevent acute complications.

IV. A second pancreas transplant after a failed primary transplant is considered **medically appropriate** in individuals who still meet transplant criteria.

V. Autologous islet cell transplantation is considered **medically appropriate** as an adjunct to a total or near-total pancreatectomy in individuals with chronic pancreatitis.

VI. Recipient Selection Guidelines:

A. Each individual considered for pancreas transplantation will have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation. Candidates considered for transplant must be psychologically stable, demonstrate motivation and compliance, and have no ongoing problems with drug or alcohol abuse.

B. The following conditions are absolute contraindications to PTA, PAK, SPK and islet cell transplantation:

1. Presence of malignancy (other than non-melanomatous skin cancers), unless malignancy has been completely resected or unless (upon medical review) it is determined that malignancy has been treated, there is a small likelihood of recurrence, and acceptable future risks;
2. Ongoing or recurring infections that are not effectively treated;
3. Serious cardiac or other insufficiencies and an inability to tolerate transplant surgery;
4. Demonstrated non-compliance, which places the organ at risk by not adhering to medical recommendations;

C. Pancreas transplant is considered a relative contraindication in human immunodeficiency virus (HIV) positive individuals, unless **ALL** of the following criteria are met:

1. CD4 count is greater than 200 cells/mm3;
2. HIV-1 ribonucleic acid RNA is undetectable;
3. stable anti-retroviral therapy for greater than three (3) months;
4. no other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); **and**
5. meets all other criteria for transplantation.

VII. Allogeneic islet cell transplantation of U.S. Food & Drug Administration (FDA) approved cellular therapy product i.e., donislecel-jujn, (Lantidra) is considered **investigational** for the treatment of type 1 diabetes.

RELATED POLICIES

Corporate Medical Policy

07.02.04 Kidney Transplantation

Pharmacy Policy

115 Lantidra

POLICY GUIDELINE(S)

I. Segmental Living Donation Guidelines:

A. Any person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ.

B. Prior authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

B. The benefits of glycemic control must be weighed against the risks associated with transplant surgery and subsequent chronic immunosuppression. The individual must demonstrate motivation and ability for self-care and have failed to obtain diabetic control.

C. A pre-emptive cadaveric or living kidney transplant should be carefully considered when the measured (actual urinary collection) creatinine clearance level or calculated GFR (or other reliable formula) is less than 30 ml/min and with a rapid rate of decline.

II. Pre-transplant evaluation documentation must include the following clinical information, and, if testing cannot be performed, the rationale for not performing the testing must be included in the documentation:

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Treatment of co-morbidities;
4. Current assessment of co-morbidities; and
5. Consult notes (if applicable).

B. Psycho-Social Evaluation:

1. Karnofsky performance score; and/or Palliative Performance Scale (PPS) score; and
2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).

C. Oral Health Evaluation:

D. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV; Hepatitis B and C; and
3. HIV Testing.

E. Cardiac Assessment:

1. 12 Lead EKG;
2. Stress test(exercise, nuclear, or dobutamine); and
3. Echo or Muga Scan.

F. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs); for high-risk for respiratory failure (COPD, emphysema, alpha-1 antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);
3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., history of smoking at least one pack per day for 20 to 30 years).

G. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) [Internet] for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2025 Feb 18]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

III. Re-Authorization

A. Transplant re-authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past eleven months (11) (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If your health condition has not changed from the previous year some testing would not be applicable.

B. Clinical Evaluation:

1. Updated list of diagnoses to include identification of comorbidities, current assessment and treatment plan.
2. Specialty consultation notes (if applicable)

C. Current functional ability as evidence by current Karnofsky performance score (KPS) or Palliative Performance Scale (PPS) score.

D. Follow- up Oral Health Evaluation.

E. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV Hepatitis B and C; and
3. HIV testing (If applicable)

F. Cardiac Assessment:

1. 12 Lead EKG (If applicable);
2. Stress (exercise, nuclear, or dobutamine) (If applicable); and
3. Echo or Muga scan (If applicable).

G. Pulmonary Assessment:

1. Chest x-ray (If applicable);
2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, alpha-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history) (If applicable); and
3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking).

H. Age-appropriate Screening Tests: Please refer to the USPSTF website for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2025 Mar 4]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

DESCRIPTION

Pancreas Transplant Alone (PTA)

A pancreas transplant is a surgical procedure that involves replacing a diseased or nonfunctioning pancreas with a healthy pancreas from a deceased or living donor. This procedure is primarily performed on individuals with IDDM who have had severe complications or are experiencing significant challenges in managing their blood sugar level. The benefits of a pancreas transplant can be not only lifesaving but can improve quality of life. A pancreas transplant can eliminate the need for insulin therapy, reduce the risk of diabetes related complications (neuropathy, retinopathy, and cardiovascular issues) and can help better manage blood sugar levels.

Pancreas transplantation is considered a therapeutic option in the management of a small group of individuals who have life-threatening or severely disabling complications from their IDDM, but who are not candidates for SPK because they do not have renal dysfunction requiring a renal transplant.

Pancreas after Kidney Transplant (PAK)

Pancreas transplant after a kidney transplant is a surgical procedure where a healthy pancreas is transplanted into an individual who has already received a kidney transplant. This approach is primarily aimed at individuals with IDDM who have undergone kidney transplantation and still

struggle with severe diabetes management. The pancreas is usually transplanted in a separate surgical procedure after a kidney transplant has taken place.

Simultaneous Pancreas and Kidney Transplant (SPK)

A SPK is a surgical procedure that involves the transplantation of both a kidney and a pancreas from a deceased donor into a single individual. This approach is primarily intended for individuals with IDDM and chronic kidney disease, or end stage renal failure. The goal is to restore kidney function, insulin production, reduce or eliminate the need for insulin therapy, improve blood glucose control and over all metabolic health. The organs are transplanted during the same surgical session. The surgeon connects the donor pancreas and kidneys to the recipient's blood vessels and urinary system. Often times, both transplanted organs may come from one deceased donor. It is also possible for the kidneys to come from a living donor (a family member or friend) and the pancreas from a deceased donor.

SPK is intended for individuals who have already developed end-stage diabetic nephropathy. The renal transplant is meant to be lifesaving, while the transplanted pancreas is indicated to slow, arrest, or reverse retinopathy or neuropathy. Additionally, the new pancreas may help the transplanted kidney function longer than if it had been transplanted without an accompanying pancreas.

There are inherent risks with all transplant surgeries, which include rejection of the new organ, infection, and complications from surgery. The individuals must take lifelong immunosuppressive medications to prevent organ rejection which can have side effects and increase the risk of infection. Transplants surgeries require careful medical management and continuous follow up to ensure the success of the transplant and overall health of the individual period.

Islet Cell Transplantation

Allotransplantation is a medical procedure in which islet cells (also called islets of Langerhan) are extracted from a deceased donor's pancreas using a specialized process. The extracted cells are then injected into the recipient's liver through the portal vein. The goal is for the transplanted islet cells to function in the liver and produce insulin. This procedure is primarily aimed at individuals with type 1 diabetes who have severe blood sugar control issues and cannot manage their condition with conventional therapies. The success of islet cell transplantation varies, with many recipients requiring insulin again within a few years after the transplantation.

U.S. Food and Drug Administration (FDA) approved Lantidra, an allogeneic (donor) pancreatic islet cellular therapy. Lantidra was approved for the treatment of adults with type 1 diabetes who are unable to approach target glycosylated hemoglobin (average blood glucose levels) because of repeated episodes of severe hypoglycemia (low blood sugar) despite intensive diabetes management and education. The primary mechanism of action of Lantidra is the secretion of insulin by the infused allogeneic islet beta cells. In some individuals with type 1 diabetes, these infused cells can produce enough insulin, so the individual no longer needs to take insulin to control their blood sugar levels. Lantidra is administered as a single infusion into the hepatic (liver) portal vein. An additional infusion of Lantidra may be performed depending on the individual's response to the initial dose. A total of

three infusions may be performed based on the individual's response. Lifelong immunosuppression is required to maintain islet cell viability.

Allogeneic islet transplantation potentially offers an alternative to whole-organ pancreas transplantation for type 1 diabetes, to restore normoglycemia and, reduce or eliminate the long-term complications of diabetes (such as retinopathy, neuropathy, nephropathy, and cardiovascular disease). A limitation of allogeneic islet transplantation is that two or more donor organs are usually required for successful transplantation, to achieve insulin independence

SUPPORTIVE LITERATURE

Pancreas Transplant

Parajuli et al. (2019) described a single center's experience with 635 pancreas and kidney transplant individuals (611 SPK, 24 PAK). Transplants were performed between 2000 and 2016. The mean length of time between kidney transplant and pancreas transplant was 23.8 months in the PAK group. Pancreas rejection rates at 1year post-transplant were 4% and 9% with PAK and SPK respectively. During the entire study period, PAK individuals were more likely to experience pancreas rejection (38% vs. 16%; p=.005). Kidney and pancreas graft survival rates did not differ between groups at 1 year or at last follow-up. Pancreas graft survival rates for PAK and SPK at 1 year were 100% and 89%, respectively. Death censored pancreas graft failure rates for PAK and SPK at last follow-up were 13% and 25%, respectively. Individual survival at last follow-up was similar between groups (71% with PAK vs. 68% with SPK; p=.79).

According to Lombardo (2021) pancreas transplantation is the most effective therapeutic option that can restore insulin independence in beta-cell phenic recipients with diabetes. Recent advancements in surgical techniques, immunosuppressive protocols and postoperative care have led to improved outcomes in transplantation, including increased rated of insulin independence and improved quality of life.

The FDA (2023) approved donislecel-jujn for the treatment of adults with type 1 diabetes who are unable to approach target HbA1C because of repeated episodes of severe hypoglycemia despite intensive diabetes management and education. The FDA approval was based on a phase 1/2 trial in individuals with brittle type 1 diabetes complicated by hypoglycemic unawareness, metabolic lability with documented severe hypoglycemia, or ketoacidosis despite intensive insulin therapy (N=10); a single-arm, open-label phase 3 trial with similar eligibility criteria (N=20); and an expanded access protocol with similar eligibility criteria.

In the FDA analysis of these trials (as described in the product labeling), median participant age was 46.5 years (range, 21 to 67 years); 80% of participants were female, 100% were White, and 97% were of non-Hispanic ethnicity. Individuals received up to 3 islet cell infusions; among 30 participants in the approval trials, 11 received 1 islet cell infusion, 12 received 2 infusions, and 7 received 3 infusions. Twenty-five participants (83%) achieved exogenous insulin independence (defined as not requiring exogenous insulin to achieve adequate glycemic control) of any duration, including 4 individuals (13.3%) with independence for less than 1 year, 12 individuals (36.7%) with

independence for 1 to 5 years, and 9 individuals (33.3%) with independence for more than 5 years. Mean duration of exogenous insulin dependence in the phase 1/2 and phase 3 studies were 5.1 years and 3.2 years respectively.

Serious adverse reactions were reported in 90%, including 2 deaths (7%) from multiorgan failure with sepsis (1.6 years after first infusion) and progressive confusion, global atrophy, and micro-ischemic disease (9.7 years after first infusion); most serious adverse reactions were attributed to immunosuppression. Infections were reported in 26 individuals (87%), totaling 211 episodes, 1 of which was classified as life-threatening and 22 as severe. Malignancy was reported in 11 subjects (37%), including 12 skin cancers and 1 each of posttransplant lymphoproliferative disease, breast cancer, and thyroid cancer. Common adverse events include, but were not limited to nausea, fatigue, anemia, diarrhea, abdominal pain, asthenia, headache, and hyponatremia. Most adverse reactions were low-grade by Common Terminology Criteria for Adverse Events, version 5; the most common grade ≥3 adverse events included low density lipoprotein elevations (37%), anemia (27%), and pneumonia (17%).

The FDA Biologics License Application Clinical Review Memorandum states numerous protocol deviations across the above studies that could impair the interpretation of both efficacy and safety data, as well as provides examples of missing and incongruent data and insufficient data monitoring during the study. The fact that the studies were conducted at a single site raises concern and, other factors that might had affect occurrence or duration of insulin independence were not able to be elucidated from the existing studies, including cell product factors (number of cells, viability, purity, and potency) and delivery device (eg, type of catheter). [accessed 2025 Feb 18]. Available from: https://www.fda.gov/vaccines-blood-biologics/lantidra

PROFESSIONAL GUIDELINE(S)

Current Organ Procurement and Transplantation Network (OPTN) policy permits HIV positive transplant candidates. The American Society of Transplantation (2019) published a guideline on solid organ transplantation in HIV-infected individuals for kidney-pancreas transplants, the following criteria for transplantation are suggested:

- Cluster of differentiation 4 count >200 cells/mL for at least 3 months (insufficient data to recommend for or against transplantation in individuals with counts >100 cells/mL and no history of opportunistic infection);
- undetectable HIV viral load while receiving antiretroviral therapy; documented compliance with a stable antiretroviral therapy regimen;
- absence of active opportunistic infection and malignancy;
- absence of chronic wasting or severe malnutrition; and appropriate follow-up with providers experienced in HIV management and ready access to immunosuppressive medication therapeutic drug monitoring (Blumberg et al. 2019).

Effective March 15, 2021, the Organ Procurement and Transplantation Network (OPTN) has launched a new policy for matching kidney and pancreas transplant candidates with organs from deceased

donors. The new policy is projected to increase equity in transplant access for candidates nationwide. It replaces distribution based on donation service area (DSA) and OPTN region with a more consistent measure of distance between the donor hospital and the transplant hospital for each candidate.

According to the 2021 American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) consensus report, β-cell replacement may serve as a therapeutic option for individuals who experience severe metabolic complications including severe hypoglycemia and hypoglycemia unawareness. Whole pancreas transplant and pancreatic islet transplantation both require lifelong immunosuppression. The ADA/EASD suggests carefully considering the risks versus benefit of β-cell replacement because of the need for chronic immunosuppression. The consensus report does note that these approaches have not been compared to newer closed-loop technology, which could avoid immunosuppression altogether.

REGULATORY STATUS

On June 28, 2023, the FDA approved Lantidra (donislecel-jujn), an allogenic pancreatic islet therapy, indicated for the treatment of adults with type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. [accessed 2025 Feb 18]. Available from: https://www.fda.gov/vaccines-blood-biologics/lantidra

Pancreas and kidney transplants, as surgical procedures, do not require U.S. Food and Drug Administration (FDA) approval. Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product or HCT/P. The Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps under 21 CFR Parts 1270 and 1271. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. CBER does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs. [accessed 2025 Feb 18]. Available from: Tissue & Tissue Products | FDA

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	with recipient nephrectomy
50370	Removal of transplanted renal allograft
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open

HCPCS Codes

Code	Description
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
S2065	Simultaneous pancreas kidney transplantation

ICD10 Codes

Code	Description
E09.21-E09.29	Drug or chemical induced diabetes mellitus with diabetic nephropathy and kidney complications (code range)
E10.10-E10.9	Type 1 diabetes mellitus (code range)
E11.00-E11.9	Type 2 diabetes mellitus (code range)
E13.00-E13.29	Other specified diabetes mellitus with hyperosmolarity, or ketoacidosis, or kidney complications (code range)
E13.40-E13.59	Other specified diabetes mellitus with neurological or circulatory complications (code range)
E13.610-E13.9	Other specified diabetes mellitus with or without other specified complications, or without complications (code range)
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M35.04	Sjogren syndrome with tubulo-interstitial nephropathy
N08	Glomerular disorders in diseases classified elsewhere
N16	Renal tubulo-interstitial disorders in diseases classified elsewhere
N18.1-N18.9	Chronic kidney disease (CKD) (code range)
T86.890-T89.899	Complications of other transplanted tissue (code range)

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Organ Procurement and Transplantation Network (OPTN). [Internet] OPTN Policies. [Updated Dec 11, 2024; [accessed 2025 Feb 18] Available from: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

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SEARCH TERMS

Kidney Transplant, Pancreas Transplant, Simultaneous Transplant, Islet Cell Transplant

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Pancreas Transplants (260.3) [accessed 2025 Feb 18]

NCD - Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1) (cms.gov) [accessed 2025 Feb 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

08/16/01, 06/20/02, 04/24/03, 02/19/04, 02/17/05, 02/16/06, 02/15/07, 01/17/08, 03/19/09, 03/18/10, 05/19/11, 05/24/12, 05/23/13, 07/17/14, 06/18/15, 05/26/16, 01/19/17, 01/18/18, 01/17/19, 01/16/20, 01/21/21, 01/20/22, 01/19/23, 03/21/24, 3/20/25

Date	Summary of Changes
03/20/25	• Annual Review, policy intent unchanged, revision of supportive literature.
01/01/25	• Summary of changes tracking implemented.
07/02/99	• Original effective date