

MEDICAL POLICY – 7.03.02

Allogeneic Pancreas Transplant

BCBSA Ref. Policy: 7.03.02

Effective Date: Nov. 1, 2024

Last Revised: Oct. 7, 2024

Replaces: Extracted from
7.03.509

RELATED MEDICAL POLICIES:


1.01.30 Artificial Pancreas Device Systems

7.03.01 Kidney Transplant

7.03.12 Islet Transplantation for Chronic Pancreatitis and Donisleccl-jujn for Type 1 Diabetes

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[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a pancreas may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

| Transplant | Medical Necessity |
|--|---|
| Pancreas transplant after a prior kidney transplant | Pancreas transplant after a prior kidney transplant may be considered medically necessary in individuals with insulin-dependent diabetes. |
| Combined pancreas and kidney transplant | A combined pancreas and kidney transplant may be considered medically necessary in insulin-dependent diabetic individuals with uremia. |
| Pancreas transplant, alone | <p>Pancreas transplant alone may be considered medically necessary in individuals with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin-dependent diabetes that persists despite optimal medical management.</p> <p>Note: See Related Information</p> |
| Pancreas retransplant | Pancreas retransplant after a failed primary pancreas transplant may be considered medically necessary in individuals who meet criteria for pancreas transplantation. |

| Transplant | Investigational |
|----------------------------|--|
| Pancreas transplant | Pancreas transplant is considered investigational in all other situations not outlined above. |

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical supporting that individual has insulin dependent diabetes (specify if Type 1 or Type 2) and if applicable the hospitalizations that occurred due to complications of hypoglycemic unawareness and/or diabetic ketoacidosis with the medication management trialed and failed, along with the specific type of pancreatic transplant being requested



Coding

| Code | Description |
|--------------|--|
| CPT | |
| 48554 | Transplantation of pancreatic allograft |
| HCPCS | |
| S2065 | Simultaneous pancreas kidney transplantation |
| S2152 | 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 posttransplant care in the global definition |

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Related Information

General Criteria

Potential contraindications for solid organ transplant that are subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage diseases not attributed to kidney disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting the ability to adhere to therapy.



Pancreas-Specific Criteria

Candidates for pancreas transplant alone should also meet one of the following severity of illness criteria:

- Documented severe hypoglycemia unawareness as evidenced by chart notes or emergency department visits or
- Documented potentially life-threatening labile diabetes, as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

Additionally, most pancreas transplant individuals will have type 1 diabetes. In 2022, individuals with type 2 diabetes accounted for 22.4% of all pancreas transplants, according to data from the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients.¹

Multiple Transplant Criteria

Although there are no standard guidelines for multiple pancreas transplants, the following information may aid in case review:

- If there is early graft loss resulting from technical factors (e.g., venous thrombosis), a retransplant may generally be performed without substantial additional risk.
- Long-term graft losses may result from chronic rejection, which is associated with increased risk of infection following long-term immunosuppression, and sensitization, which increases the difficulty of finding a negative cross-match. Some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

Benefit Application

See individual's plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.



Description

Transplantation of a healthy pancreas is a treatment for individuals with insulin-dependent diabetes. Pancreas transplantation can restore glucose control and prevent, halt, or reverse the secondary complications from diabetes.

Background

Solid organ transplantation

Solid organ transplantation offers a treatment option for individuals with different types of end-stage organ failure that can be lifesaving or provide significant improvements to an individual's quality of life.² Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Allogeneic Pancreas Transplant

In 2023, 46,630 transplants were performed in the United States procured from more than 16,000 deceased donors and 6,900 living donors.³ Pancreas-kidney transplants were the fifth most common procedure, with 812 transplants performed in 2023. Pancreas-alone transplants were the sixth most common procedure, with 102 transplants performed in 2023.

Pancreas transplantation occurs in several different scenarios such as (1) a diabetic individual with renal failure who may receive a simultaneous cadaveric pancreas plus kidney transplant; (2) a diabetic individual who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney); or (3) a nonuremic diabetic individual with specific severely disabling and potentially life-threatening diabetic problems who may receive a pancreas transplant alone.

Data from the United Network for Organ Sharing and the International Pancreas Transplant Registry indicate that the proportion of simultaneous pancreas plus kidney transplant recipients worldwide who have type 2 diabetes has increased over time, from 6% of transplants between



2005 and 2009 to 9% of transplants between 2010 and 2014.⁴ Between 2010 and 2014, approximately 4% of pancreas after kidney transplants and 4% of pancreas alone transplants were performed in patients with type 2 diabetes. In 2022, patients with type 2 diabetes accounted for 22.4% of all pancreas transplants, according to data from the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients.¹

Summary of Evidence

For individuals who have insulin-dependent diabetes who receive a pancreas transplant after a kidney transplant, the evidence includes retrospective studies and registry studies. The relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high individual survival rates with a pancreas transplant after a kidney transplant (e.g., a 3-year survival rate of 94.5%). Single-center retrospective studies have found similar individual survival and death-censored pancreas graft survival rates with a pancreas transplant after a kidney transplant or a simultaneous pancreas and kidney (SPK) transplant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have insulin-dependent diabetes with uremia who receive SPK transplants, the evidence includes retrospective studies and registry studies. The relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high individual survival rates after SPK transplant. A retrospective analysis found a higher survival rate in individuals with type 1 diabetes who had an SPK transplant vs those on a waiting list. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have insulin-dependent diabetes and severe complications who receive pancreas transplant alone (PTA), the evidence includes registry studies. The relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. Data from international and national registries have found that graft and individual survival rates after PTA have improved over time (e.g., three-year survival of 94.9%). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had a prior pancreas transplant who still meet criteria for a pancreas transplant who receive pancreas retransplantation, the evidence includes retrospective studies and registry studies. The relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. National data and specific transplant center data have generally found similar graft and individual survival rates after pancreas retransplantation compared with initial transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.



Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|-----------------------------|--|--------------------|-----------------|
| Ongoing | | | |
| NCT01047865 | Recurrence of T1D in Pancreas Transplantation | 400 | May 2025 |
| NCT01957696 | A Prospective, Observational Study in Pancreatic Allograft Recipients: The Effect of Risk Factors, Immunosuppressive Level and the Benefits of Scheduled Biopsies - on Surgical Complications, Rejections and Graft Survival | 80 | Oct 2028 |
| Unpublished | | | |
| NCT00238693 | Transplant Registry: Patients Who May Require Transplantation and Those Who Have Undergone Transplantation of Liver, Kidney and/or Pancreas | 13,767 | Aug 2018 |
| NCT03921593 | Prospective Longitudinal Observational Study on Insulin Dependent Diabetic Patients Undergoing Any Form of Solid Organ Pancreas Transplantation Aimed to Clarify Quality of Life Changes After Pancreas Transplantation | 110 | Mar 2022 |

NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence. Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.



Organ Procurement and Transplantation Network

The Organ Procurement and Transplantation Network updated its comprehensive list of transplant-related policies, most recently in May 2024.²⁵

For pancreas registration:

"Each candidate registered on the pancreas waiting list must meet one of the following requirements:

- Be diagnosed with diabetes
- Have pancreatic exocrine insufficiency
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons."

For combined kidney plus pancreas registration: "Each candidate registered on the kidney-pancreas waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency."

Medicare National Coverage

An allogeneic pancreas transplant is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria.³² The Centers for Medicare & Medicaid Services made the following national coverage decision on pancreas transplant for Medicare recipients.³³

A. General

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.

B. Nationally Covered Indications

Effective ...1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneously with or after a kidney transplant. If the pancreas transplant occurs



after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective ...2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation.
2. Patients must have a diagnosis of type I diabetes:
 - Patient with diabetes must be beta-cell autoantibody-positive; or
 - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL;
3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
4. Patients 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. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,
6. Patients must otherwise be a suitable candidate for transplantation."

Nationally noncovered indications include "Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial)."

Regulatory Status

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the US Food and Drug Administration (FDA).



The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

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History



| Date | Comments |
|----------|---|
| 11/01/19 | New policy, approved October 4, 2019. Content previously addressed in policy 7.03.509. Policy created with literature review through June 2019. Pancreas transplantation may be considered medically necessary when criteria are met, considered investigational when criteria are not met. Policy statement on transplantation of HCV viremic organs is taken from BCBSA policy 7.03.14. |
| 11/01/20 | Annual Review, approved October 22, 2020. Policy updated with literature review through June, 2020; references added; Policy statements unchanged. |
| 11/01/21 | Annual Review, approved October 5, 2021. Policy updated with literature review through June 22, 2021; references added; Policy statements unchanged. |
| 11/01/22 | Annual Review, approved October 10, 2022. Policy updated with literature review through June 21, 2022; no references added. Minor editorial refinements to policy statements; intent unchanged. Changed policy wording from "patient" to "individual" for standardization. |
| 11/01/23 | Annual Review, approved October 9, 2023. Policy updated with literature review through June 30, 2023; no references added. Removed the policy statement regarding the transplantation of HCV-viremic solid organs to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational. Otherwise, policy statements unchanged. |
| 11/01/24 | Annual Review, approved October 7, 2024. Policy updated with literature review through June 24, 2024; references added. Policy statements unchanged. |

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

