



MASSACHUSETTS

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## Medical Policy

# Allogeneic Pancreas Transplant

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### Policy Number: 328

BCBSA Reference Number: 7.03.02 (For Plan internal use only)

### Related Policies

- Artificial Pancreas Device Systems, #[107](#)
- Kidney Transplant, #[196](#)
- Islet Transplantation, #[324](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

A combined pancreas-kidney transplant may be **MEDICALLY NECESSARY** in insulin dependent diabetic individuals with uremia.

Pancreas transplant after a prior kidney transplant may be **MEDICALLY NECESSARY** in individuals with insulin dependent diabetes.

Pancreas transplant alone may be **MEDICALLY NECESSARY** in individuals with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin-dependent diabetes that persists in spite of optimal medical management.

Pancreas retransplant after a failed primary pancreas transplant may be **MEDICALLY NECESSARY** in individuals who meet criteria for pancreas transplantation.

In addition to the above information, we do not cover pancreas transplantation when **any** of the following conditions are present:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence

- Note: the assessment of risk of recurrence for a previously treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease 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 ability to adhere to therapy.

### Policy Guidelines

Candidates for pancreas transplant alone should additionally meet 1 of the following severity of illness criteria:

- Documentation of severe hypoglycemia unawareness as evidenced by chart notes or emergency department visits, **OR**
- Documentation of 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.<sup>1</sup>

Pancreas transplant is considered **INVESTIGATIONAL** in all other situations.

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
<b>Commercial Managed Care (HMO and POS)</b>	This procedure is performed in the inpatient setting.
<b>Commercial PPO and Indemnity</b>	This procedure is performed in the inpatient setting.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

#### CPT Codes

CPT codes:	Code Description
48554	Transplantation of pancreatic allograft

## HCPCS Codes

HCPCS codes:	Code Description
S2065	Simultaneous pancreas kidney transplantation

## ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0FYG0Z0	Transplantation of Pancreas, Allogeneic, Open Approach
0FSG0ZZ	Reposition Pancreas, Open Approach
0FSG4ZZ	Reposition Pancreas, Percutaneous Endoscopic Approach

## Description

### Solid Organ Transplantation

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life.<sup>2</sup> 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. Patients 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.<sup>3</sup> 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 patient with renal failure who may receive a simultaneous cadaveric pancreas plus kidney transplant; (2) a diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney); or (3) a nonuremic diabetic patient 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.<sup>4</sup> 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.<sup>1</sup>

## Summary Description

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

### 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. Relevant outcomes are overall survival (OS), change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates with a pancreas transplant after a kidney transplant (eg, a 3-year survival rate of 94.5%). Single-center retrospective studies have found similar patient 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. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates after SPK transplant. A retrospective analysis found a higher survival rate in patients with type 1 diabetes who had an SPK transplant versus 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, the evidence includes registry studies. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from international and national registries have found that graft and patient survival rates after pancreas transplant alone have improved over time (eg, 3-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. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. National data and specific transplant center data have generally found similar graft and patient 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.

### Policy History

Date	Action
10/2024	Annual policy review. Policy updated with literature review through June 24, 2024; references added. Policy Guidelines updated to remove obesity-related criteria.
10/2023	Annual policy review. Description, summary, and references updated. Policy statement unchanged.
10/2022	Annual policy review. No references added. Minor editorial refinements to policy statements; intent unchanged.
9/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.

10/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2017	Annual policy review. New references added.
5/2015	Clarified coding language.
4/2015	Annual policy review. Clarified that pancreas transplant is investigational in all other situations. Effective 4/1/2015.
10/2014	Medical policy remediation: New indications for non-coverage. Coding information clarified. Effective 10/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	Annual policy review. Medically necessary indications clarified. Effective 4/1/2014. Coding information clarified
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
5/2011	Annual policy review. Changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
6/2009	Annual policy review. No changes to policy statements.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
4/2008	Annual policy review. No changes to policy statements.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

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