

02-40000-17

Original Effective Date: 07/15/02

Reviewed: 04/24/25

Revised: 05/15/25

Subject: Allogeneic Pancreas Transplant

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

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

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

POSITION STATEMENT:

Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

Pancreas transplant after a prior kidney transplant **meets the definition of medical necessity** in individuals with insulin-dependent diabetes.

A combined pancreas and kidney transplant **meets the definition of medical necessity** in insulin-dependent diabetic individuals with end stage renal disease (ESRD).

Pancreas transplant alone **meets the definition of medical necessity** 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, **AND** who meet one the following:

- 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

Pancreas retransplant after a failed primary pancreas transplant **meets the definition of medical necessity** in candidates who meet criteria for pancreas transplantation.

Pancreas, pancreas-kidney and pancreas after kidney transplantation is considered **experimental or investigational** in all other situations, as available clinical evidence does not support safety and effectiveness.

Potential contraindications to pancreas and pancreas-kidney transplant (subject to the judgment of the transplant center) include:

- 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 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

BILLING/CODING INFORMATION:

CPT Coding:

48550	Donor pancreatectomy (including cold preservation) with or without duodenal segment for transplantation
48551	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 anastomosis from iliac artery to superior mesenteric artery and to splenic artery

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
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft with recipient nephrectomy

HCPCS Coding:

S2065	Simultaneous pancreas kidney transplantation
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REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Pancreas Transplants (260.3), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

End Stage Renal Disease (ESRD): The terms end-stage renal failure and end-stage renal disease are used interchangeably; there is persistent decline in renal function with falling creatinine clearance in an individual who is expected to progress to requiring dialysis or transplant. Typically, those with ESRD will have kidney function in the area of 10-15%.

Hypoglycemia unawareness: A condition in which a person with diabetes doesn't experience the usual warning symptoms of hypoglycemia; may lead to confusion, disorientation or loss of consciousness.

Labile insulin-dependent diabetes: Diabetes that is particularly hard to control, with frequent, extreme swings in blood glucose levels; also called brittle diabetes.

RELATED GUIDELINES:

[Kidney Transplant, 02-50300-01](#)

[Small Bowel, Liver and Multivisceral Transplant, 02-40000-19](#)

OTHER:

Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

Florida Statute 627.64197 Coverage for organ transplants.—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 627.65736 Coverage for organ transplants.—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 641.31075 Coverage for organ transplants.—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

REFERENCES:

1. American Diabetes Association. Pancreas transplantation for patients with type 1 diabetes (Position Statement). *Diabetes Care*. 2003; 26 (Suppl 1): S120.
2. Andreoni KA, et al. Kidney and pancreas transplantation in the United States, 1996-2005. *American Journal of Transplantation* 2007; 7 (part 2): 1359-1375.
3. Aref A, Zayan T, Pararajasingam R, Sharma A, Halawa A. Pancreatic transplantation: Brief review of the current evidence. *World journal of transplantation*. 2019 Aug 26;9(4):81.
4. Awata T, Kenmochi T, et al. Pancreas transplantation for type 1 diabetes in Japan: past, present and future prospects. *Glob Health Med*. 2020 Dec 31;2(6):360-366. doi: 10.35772/ghm.2020.01069.
5. Bahar SG, Devulapally P. Pancreas Transplantation. 2021 May 23. In: *StatPearls [Internet]*. Treasure Island (FL): StatPearls Publishing; 2021 Jan.
6. Banga N, et al. Outcome of surgical complications following simultaneous pancreas–kidney transplantation. *Nephrol Dial Transplant* (2012) 27: 1658–1663.
7. Barlow AD, Saeb-Parsy K, Watson CJ. An analysis of the survival outcomes of simultaneous pancreas and kidney transplantation compared to live donor kidney transplantation in patients with type 1 diabetes: a UK Transplant Registry study. *Transplant International*. 2017 Sep;30(9):884-92.

8. Barnes Jewish Hospital Transplant Center. Simultaneous Pancreas/Kidney (SPK) Transplantation Candidate Criteria. Accessed at <http://www.barnesjewish.org/criteria-for-kidney-pancreas-transplant>.
9. Blue Cross Blue Shield Association Evidence Positioning System®. 7.03.02, Allogeneic Pancreas Transplant, 09/24.
10. Canadian Agency for Drugs and Technology in Health. Pancreas Transplantation to Restore Glucose Control: Review of Clinical and Economic Evidence. 2007. Accessed at: http://cadth.ca/media/pdf/l3005_Pancreatic_Transplantation_tr_e.pdf.
11. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for PANCREAS TRANSPLANTS (260.3) (04/26/06).
12. Florida State Statutes 765.523 – Discrimination in access to anatomical gifts and organ transplants prohibited; Florida Statute 627.64197 – Coverage for organ transplants; 627.65736 – Coverage for organ transplants; and 641.31075 – Coverage for organ transplants. Accessed at <http://www.flsenate.gov/>.
13. Fourtounas C. Transplant options for patients with type 2 diabetes and chronic kidney disease. *World J Transplant* 2014 June 24; 4(2): 102-110.
14. Gasteiger S, Cardini B, Göbel G, et al. Outcomes of pancreas retransplantation in patients with pancreas graft failure. *Br J Surg*. 2018 Dec;105(13):1816-1824.
15. Gaston RS, et al. Transplantation in the Diabetic with Advanced Chronic Kidney Disease: A Task Force Report. *Am J Kidney Dis* 44: 529-542.
16. Gruessner AC, Sutherland DE. Access to pancreas transplantation should not be restricted because of age. *Transplant Int* 2011; 24(2):134-35.
17. 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 Transplant Registry. *Rev Diabet Stud* 2011; 8(1):6-16.
18. HAYES, Inc. Medical Technology Directory. Pancreas After Kidney Transplantation. Lansdale, PA: Hayes Inc: 06/30/06 (updated 07/27/07).
19. HAYES, Inc. Medical Technology Directory. Pancreas Transplantation, Alone and After Kidney Transplantation. Lansdale, PA: Hayes Inc. (PAK, 02/26/99; PTA 03/1/99; updated 08/13/03).
20. HAYES, Inc. Medical Technology Directory. Pancreas Transplantation Alone. Lansdale, PA: Hayes Inc. 02/27/06 (updated 03/04/08).
21. HAYES, Inc. Medical Technology Directory. Simultaneous Pancreas-Kidney Transplantation in Diabetic Patients Lansdale, PA: Hayes Inc: 06/21/06 (updated 01/22/08).
22. Isla Pera A, et al. Impact of simultaneous pancreas-kidney transplantation: patients' perspectives. *Patient Preference and Adherence* 2012;6 597–603.
23. Jiang AT, et al. Simultaneous pancreas-kidney transplantation: The role in the treatment of type 1 diabetes and end-stage renal disease. *Can Urol Assoc J* 2014;8(3-4):135-8.
24. Johns Hopkins Medicine Comprehensive Transplant Center. Kidney and Pancreas Patient Selection Criteria. Accessed at http://www.hopkinsmedicine.org/transplant/referring_physicians/patient_selection_criteria/kidney_pancreas.html.
25. Khairoun M, et al. Microvascular Damage in Type 1 Diabetic Patients Is Reversed in the First Year After Simultaneous Pancreas–Kidney Transplantation. *American Journal of Transplantation* 2013; 13: 1093–1281.
26. Mai ML, et al. The long-term management of pancreas transplantation. *Transplantation* 2006; 82: 991-1003.

27. Nakamura T, Fujikura J, Inagaki N. Advancements in transplantation therapy for diabetes: Pancreas, islet and stem cell. J Diabetes Investig. 2021 Feb;12(2):143-145. doi: 10.1111/jdi.13358. Epub 2020 Aug 27.
28. National Kidney Foundation. Kidney-Pancreas Transplant. Accessed at <https://www.kidney.org/atoz/content/kidpantx>.
29. Organ Procurement and Transplantation Network (OPTN). Kaplan-Meier Graft Survival Rates For Transplants Performed 1997 – 2004. Accessed at: <http://optn.transplant.hrsa.gov/latestData/viewDataReports.asp>.
30. Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DE. Pancreas and islet transplantation type 1 diabetes. Diabetes care. 2006 Apr 1;29(4):935.
31. Sampaio MS, Kuo HT, Bunnapradist S. Outcomes of simultaneous pancreas-kidney transplantation in type 2 diabetic patients. Clin J Am Soc Nephrol 2011; 6(5):1198-206.
32. Schenker P, Vonend O, Kruger B et al. Long-term results of pancreas transplantation in patients older than 50 years. Transplant Int 2011; 24(2):136-42.
33. Organ Procurement and Transplantation Network Policies (04/10/14). Accessed at: <http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>.
34. Organ Procurement and Transplantation Network (OPTN) Policies: Organ distribution: pancreas allocation. Updated 2013 Jul 25. Accessed at: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_10.pdf.
35. UpToDate. Pancreas and islet transplantation in diabetes mellitus. 2025. Accessed at [uptodate.com](https://www.uptodate.com).
36. UpToDate. Pancreas-kidney transplantation in diabetes mellitus: Benefits and complications. 2025. Accessed at [uptodate.com](https://www.uptodate.com).
37. UpToDate. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pretransplant evaluation. 2025. Accessed at [uptodate.com](https://www.uptodate.com).
38. van Dellen D, Worthington J, Mitu-Pretorian OM et al. Mortality in diabetes: pancreas transplantation is associated with significant survival benefit. Nephrol Dial Transplant 2013; 28(5):1315-22.
39. Waki K, et al. Long-Term Pancreas Allograft Survival in Simultaneous Pancreas-Kidney Transplantation by Era. Diabetes Care 33:1789–1791, 2010.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/24/25.

GUIDELINE UPDATE INFORMATION:

07/15/01	Medical Coverage Guideline Reformatted.
03/15/02	Change to covered services section.
06/15/03	Reviewed; removed investigational statement for islet cell transplantation for development of separate MCG.
04/15/04	Scheduled review with formatting revisions; added investigational statement regarding transplants in HIV-positive recipients.

01/01/05	HCPCS coding update: added new codes 48551 and 48552; revised code 48550 descriptor.
04/15/05	Scheduled review; no change in coverage statement.
06/15/05	Revision of guideline, consisting of removal of investigational statement regarding HIV-positive recipients.
06/15/06	Scheduled review; no change in coverage statement.
06/15/07	Scheduled review; reformatted guideline; updated references.
07/15/08	Scheduled review. Delete experimental or investigational position for 2 or more failed pancreas transplants. Add language for multiple transplants. Update references.
06/15/09	Scheduled review; no change in position statement.
06/15/10	Annual review; no change in position statement. References updated.
06/15/14	Scheduled review. Revised MCG title, description, position statement, program exceptions and definitions section. Updated references.
12/15/14	Unscheduled review. Revised position statement (SPK criteria). Revised definitions and updated references.
12/15/19	Scheduled review. Revised description, maintained position statement, and updated references.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical gifts and coverage of organ transplants. Updated references.
09/15/21	Scheduled review. Maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
08/15/23	Scheduled review. Maintained position statement and updated references.
05/15/25	Scheduled review. Maintained position statement and updated references.