Preauthorization is required and must be obtained through Case Management.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOLS

Artificial Pancreas Device Systems
Islet Transplantation
Kidney Transplant

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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 (e.g., 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 a 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 (e.g., 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
Pancreas transplant after a prior kidney transplant may be considered medically necessary in patients with insulin-dependent diabetes.

A combined pancreas and kidney transplant may be considered medically necessary in insulin-dependent diabetic patients with uremia.

Pancreas transplant alone may be considered medically necessary in patients 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 considered medically necessary in patients who meet criteria for pancreas transplantation.
Pancreas transplant is considered **investigational** in all other situations.

**POLICY GUIDELINES**

**GENERAL**

Individual transplant facilities may have their own additional requirements or protocols that must be met in order for the patient to be eligible for a transplant at their facility.

Potential contraindications subject to the judgment of the transplant center:

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

**PANCREAS SPECIFIC CRITERIA**

Candidates for pancreas transplant alone should additionally meet one 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 patients will have type 1 diabetes mellitus. Those transplant candidates with type 2 diabetes mellitus, in addition to being insulin-dependent, should also not be obese (body mass index [BMI] should be 32 kg/m² or less). According to International Registry data, in 2010, 7% of pancreas transplant recipients had type 2 diabetes (Gruessner, 2011).

**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.

**MEDICARE ADVANTAGE**

If a transplant is needed, we arrange to have the Medicare–approved transplant center review and decide whether the patient is an appropriate candidate for the transplant.
BACKGROUND

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. 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 2019, 39,719 transplants were performed in the United States procured from almost 11,900 deceased donors and 7,400 living donors. Pancreas-kidney transplants were the fifth most common procedure, with 872 transplants performed in 2019. Pancreas-alone transplants were the sixth most common procedure, with 143 transplants performed in 2019.

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. 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 2019, patients with type 2 diabetes accounted for 20.6% of all pancreas transplants, according to data from the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. Patients with type 2 diabetes accounted for 6.2%, 1%, and 22.4% of pancreas alone, pancreas after kidney, and simultaneous pancreas plus kidney transplants, respectively.

REGULATORY STATUS

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced...
procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**REFERENCES**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

32. Gruessner AC, Sutherland DE. Access to pancreas transplantation should not be restricted because of age: invited commentary on Schenker et al. Transpl Int. Feb 2011;24(2):134-5. PMID 21208293