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Kaiser Foundation Health Plan of Washington

Patient Referral Guidelines
Pancreas Transplant Alone

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pancreas Transplants (260.3)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, accepted guidelines for Pancreas Transplant Alone and Pancreas After Kidney transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. It is important to note that these are guidelines and should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection is a contraindication to transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low.[1,2,3] Exceptions may be made on a case-by-case basis.
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
   g. Patients must be able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
   h. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
   i. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

Back to Top

j. Evidence of such non adherence may be: failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list
k. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. PANCREAS TRANSPLANT ALONE (PTA/PAK)
   a. Indications for PTA/PAK Transplant
      i. Type 1 DM with disabling and potentially life threatening complications as seen in brittle diabetes with severe and recurrent episodes of either hypoglycemia (involving seizures, loss of consciousness and/or calls to 911) and or hyperglycemia (episodes of DKA) or hypoglycemic unawareness in which the individual requires constant supervision.
      ii. Optimally and intensively managed by an endocrinologist for at least 12 months[4].
      iii. Age 18 - 55 except under special clinical circumstances.
      iv. Native or transplanted kidney must be functioning well as evidenced by an accepted formula for GFR or a 24-hour urine for creatinine clearance of >50 ml per minute[5,6,7]
3. Contraindications for PTA/PAK Transplant
   a. Significant irreversible coronary artery disease and/or left ventricular dysfunction, and irreversible pulmonary disease.
   b. Irreversible peripheral vascular disease, including carotid vascular disease (Amputation alone is not a contraindication).
   c. Uncontrolled hypertension.

   Relative Contraindications
   a. BMI ≥ 35. Patients may be referred to the COE for individual consideration.
      i. May be concurrently referred for weight loss intervention.
   b. Cachexia and/or malnourishment

1. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
2. *Liver Transplant Surg,*. 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
4. National Coverage Determination (NCD) for Pancreas Transplants (260.3) version 3. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?
5. An assessment of the effect on renal function of a calcineurin inhibitor may be required for a creatinine clearance or GFR between 50 and 70 ml/minute.
6. As determined by direct measurement or calculated by an accepted formula, such asthe CKD-EPI creatinine equation (2021) that are refitted without race.
7. National Kidney Foundation, eGFR Calculator: https://www.kidney.org/professionals/kdoqi/gfr_calculator

If requesting these services, please send the following documentation to support medical necessity:

- Copy of final summary report from multidisciplinary transplant team

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Pancreas transplantation is used in patients with type 1 diabetes. After a successful transplantation, many diabetic patients no longer require insulin. Due to the danger of organ rejection in the short- or long-term, pancreas transplant recipients need to take immunosuppressive drugs.

Most pancreas transplants are done in conjunction with (at the same time or following) a kidney transplant. A reason for this combination transplant is that the pancreas induces a strong immune response and therefore requires larger doses of immunosuppressive drugs that can jeopardize kidney function and the transplanted pancreas.

The first clinical pancreas transplant (of any type) was done in 1966. Initially there was a low success rate but clinical outcomes improved in the 1980s due to advances in surgical techniques and the introduction of

 Back to Top

cyclosporine for immunosuppression. Newer immunosuppressants, Tacrolimus and mycophenolate mofetil, were introduced in 1994 and 1995, respectively. Since 1994, there have been improved graft survival rates in patients receiving pancreas transplants alone (PTA).

Medical Technology Assessment Committee (MTAC)

Pancreas Transplant

12/12/2001: MTAC REVIEW

Evidence Conclusion: Only one article reported data on patients receiving pancreas transplants alone. The methodology was not well described, and the intervention procedures varied dramatically over time. The article reported on the experience of the institution; it was primarily a review article rather than a research study. The case series portion of this article had inadequately described methodology and is subject to selection and observation biases. Due to lack of quality scientific data, the evidence is insufficient to draw conclusions about the effect of this technology on health outcomes.

Articles: The search yielded 36 articles, many of which were review articles, opinion pieces or dealt with pancreas transplantation in conjunction with kidney transplantation. There were no empirical studies that presented separate data on the outcomes of PTA. There were several case series that included both pancreas transplantation in conjunction with kidney transplantation and PTA, but the data were not divided by type of procedure. Only one article presented some data separately for patients receiving PTA. This was primarily a review article and included case series data. This study was critically appraised:

Sutherland DER, Gruessner RWG, Dunn DL, Matas AJ, Humar A, Kandaweamy R, Mauer M, Kennedy WR, Goetz FC, Robertson RP, Gruessner AC, Najarian JS. Lessons learned from more than 1,000 pancreas transplants at a single institution. Ann Surg 2001; 233: 463-501.

The use of Pancreas Transplant alone in the treatment of Juvenile Diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
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 anastomoses 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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/12/2001	10/05/2010 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 11/03/2015 MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/02/2019MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC, 12/03/2024MPC	01/10/2022

MDCRPC Medical Director Clinical Review and Policy Committee

Back to Top

Revision History	Description
05/07/2019	MPC approved KP National criteria for Pancreas Transplant.
03/03/2020	MPC approved proposed changes from KP National Transplant Services
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”
01/10/2022	MPC approved proposed changes from KP National Transplant Services. 60-day notice is not required.

Back to Top