



## **PATIENT REFERRAL GUIDELINES**

### **Kidney/Pancreas Transplant**

**NOTICE:** Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

### **Criteria**

#### **For Medicare Members**

<b>Source</b>	<b>Policy</b>
CMS Coverage Manuals	<a href="#">Medicare Benefits Manual Chapter 11 – End Stage Renal Disease Section 140 - Transplantation</a>
National Coverage Determinations (NCD)	<a href="#">Pancreas Transplants (260.3)</a>
Local Coverage Determinations (LCD)	None

#### **For Non-Medicare Members**

Note: Simultaneous Pancreas Kidney Transplantation (SPK)<sup>1</sup>

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. 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. Patient and treating physician should understand the uncertain benefits of successful pancreas transplantation beyond glucose control.

#### **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<sup>2,3,4</sup>. 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. Patient must be willing and 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.

- 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

## 2. INDICATIONS FOR SPK TRANSPLANT

- a. Type 1 (as verified by stimulated C-peptide testing or presence of antibodies to glutamic acid decarboxylase, islet cell, insulin, etc.) diabetes mellitus with or approaching end stage renal disease. A diagnosis of Type 1.5 diabetes mellitus may be needed by endocrinology.
  - 1. In selective situations, known Type 2 Diabetes Mellitus patients (also referred to as Type 1.5 DM) with low C peptide and a low BMI (<28), requiring low dose insulin with end stage renal disease or advanced CKD may be considered for SPK.
- b. Optimally and intensively managed by an endocrinologist for at least 12 months for Type 1 diabetes mellitus.<sup>5</sup>
- c. Age 18-55, except under special clinical circumstances.
- d. Must be a candidate for kidney transplantation. Patients cannot be listed on the UNOS waiting list for a deceased donor kidney until their estimated GFR, calculated by the CKD-EPI creatinine equation (2021) that are refitted without race or the CKD-EPI creatinine-cystatin equation (2012) that are refitted without race, is less than 20ml/min.<sup>6,7,8</sup>

### CONTRAINDICATIONS FOR SPK 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 FOR SPK TRANSPLANT

- a. BMI  $\geq$  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

#### Footnotes

- 1. In certain situations where the NTS COE recommends, in discussion with the patient, to proceed with a staged transplant procedure (living donor kidney followed by cadaveric pancreas transplant) due to organ availability, the patient will need to meet the indications for a SPK transplant.
- 2. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
- 3. *Liver Transplant Surg.* 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
- 4. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
- 5. National Coverage Determination (NCD) for Pancreas Transplants (260.3) version 3. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?>
- 6. Inker, Lesley A., et al., "New Creatinine- and Cystatin C–Based Equations to Estimate GFR without Race." *N Engl J Med* 2021; DOI: 10.1056/NEJMoa2102953
- 7. Hsu, Chi-yuan, et al., "Race, Genetic Ancestry, and Estimating Kidney Function in CKD." *N Engl J Med* 2021; DOI: 10.1056/NEJMoa2103753
- 8. National Kidney Foundation, eGFR Calculator: [https://www.kidney.org/professionals/kdoqi/gfr\\_calculator](https://www.kidney.org/professionals/kdoqi/gfr_calculator)

#### If requesting this service, 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

## Background

This service is covered when it is medically necessary and identified as a benefit in the consumer's coverage contract. The Kaiser Permanente Nephrologists in collaboration with the Kaiser Permanente Transplant Committee and the Transplant Centers define the Kaiser Permanente patient referral guidelines.

## Evidence and Source Documents

Kaiser Permanente Committee on Emerging Technology

Transplant, simultaneous Pancreas/Kidney (SPK) - 7/11/1990

Simultaneous pancreas/kidney transplantation is approved for diabetic patients who otherwise would be candidates for a kidney transplant, subject to review in six months.

The University of Washington transplant criteria set are used as a source document and updated when new efficacy data becomes available by the Kaiser Permanente Nephrology section with approval by the Kaiser Permanente Transplant Committee.

## Applicable Codes

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

CPT® Codes	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor *subject to <a href="#">Elective Surgical Procedure Level of Care review</a>
48550	Donor pancreatotomy (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
HCPC Codes	Description
S2065	Simultaneous pancreas kidney transplantation <b>*S codes not covered by Medicare</b>

**\*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](#).**

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
07/11/1997	04/05/2010 <sup>MDCRPC</sup> , 08/02/2011 <sup>MDCRPC</sup> , 06/05/2012 <sup>MDCRPC</sup> , 04/02/2013 <sup>MDCRPC</sup> , 02/04/2014 <sup>MPC</sup> , 12/02/2014 <sup>MPC</sup> , 10/06/2015 <sup>MPC</sup> , 08/02/2016 <sup>MPC</sup> , 06/06/2017 <sup>MPC</sup> , 04/03/2018 <sup>MPC</sup> , 04/02/2019 <sup>MPC</sup> , 04/07/2020 <sup>MPC</sup> , 04/06/2021 <sup>MPC</sup> , 04/05/2022 <sup>MPC</sup> , 04/04/2023 <sup>MPC</sup>	01/10/2022

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt Kaiser Permanente National coverage policy
06/12/2020	Added "Patient Referral Guidelines" to title; changed background from patient selection criteria to patient referral guidelines
04/06/2021	Per National Transplant Guidelines: 1.3 added "active"
01/10/2022	MPC approved the proposed changes from KP National Transplant Services. 60-day notice is not required.