Medical Coverage Policy

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Kidney Transplantation, Pancreas-Kidney Transplantation, and Pancreas Transplantation Alone

Table of Contents

Related Coverage Resources

Liver and Liver-Kidney Transplantation
Pancreatic Islet Cell Transplantation
Plasmapheresis

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined

in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses kidney transplantation, pancreas-kidney transplantation, and pancreas transplantation alone.

- See CP 0355 for Liver-kidney transplantation.
- See CP 0107 for Pancreatic Islet Cell Transplantation.

Coverage Policy

KIDNEY TRANSPLANTATION

Kidney transplantation is considered medically necessary when ANY of the following criteria are met:

- adults (i.e., >18 years of age) measured or calculated creatinine clearance or glomerular filtration rate (GFR) less than or equal to 20 mL/min/1.73m^2.
- pediatric (i.e., ≤18 years of age) stage 4 chronic kidney disease (estimated GFR <30 mL/min per 1.73m^2)
- end-stage renal disease (ESRD) on regularly administered dialysis

SIMULTANEOUS PANCREAS-KIDNEY (SPK) TRANSPLANTATION

Simultaneous pancreas-kidney (SPK) transplantation is considered medically necessary when BOTH of the following criteria are met:

- medical necessity for kidney transplantation is met, and
- EITHER of the following indications:
  - diabetes mellitus (if individual is at least 18 years old must be on insulin)
  - pancreatic exocrine insufficiency

PANCREAS TRANSPLANTATION ALONE (PTA)

Pancreas transplantation is considered medically necessary for an individual who meets ONE of the following criteria:

- diabetes mellitus (if individual is at least 18 years old must be on insulin)
- pancreatic exocrine insufficiency
- requires the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

PANCREAS-AFTER-KIDNEY (PAK) TRANSPLANTATION

Pancreas-after-kidney transplantation (PAK) is considered medically necessary when pancreas transplantation criteria are met.

KIDNEY, SIMULTANEOUS PANCREAS-KIDNEY (SPK), PANCREAS TRANSPLANTION ALONE (PTA), OR PANCREAS-AFTER-KIDNEY TRANSPLANTATION

Kidney transplantation, simultaneous pancreas-kidney transplantation (SPK), pancreas transplantation alone (PTA), and pancreas-after-kidney (PAK) transplantation is considered medically necessary if an individual with a history of malignancy:

- meets the above criteria for kidney transplantation, simultaneous pancreas-kidney transplantation (SPK), pancreas transplantation alone (PTA), and pancreas-after-kidney (PAK) transplantation AND
- has oncology clearance in accordance with published guidelines (See Appendix) and does not have a contraindication as noted below.

Not Covered

Kidney, pancreas, or pancreas-kidney transplantation for an individual with ANY of the following contraindications to transplant surgery is considered not medically necessary:

- a history of the following malignancies (See Appendix):
    - Breast cancer, Stage IV
    - Prostate cancer, metastatic and castration-resistant
    - Renal cell carcinoma:
        - with sarcomatoid and/or rhabdoid histologic features
        - duct or medullary
    - Bladder cancer, muscle invasive
    - Gynecological cancer:
        - Endometrial cancer:
            - Stage IV
            - recurrent or metastatic
        - Ovarian cancer:
            - epithelial, Stage IV
            - recurrent
        - Cervical cancer:
            - Squamous cell/adenocarcinoma, Stage IV
            - recurrent or metastatic
    - Lung cancer, Stage IIIA or higher
    - Skin cancer:

    - Cutaneous squamous cell carcinoma with distant metastasis
    - Merkel cell carcinoma with distant metastasis
    - Malignant melanoma, Stage III or IV

- persistent, recurrent or unsuccessfully treated major or systemic extra-renal infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
- a pattern of demonstrated patient noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless ALL of the following are noted:
    - CD4 count greater than 200 cells/mm^3
    - HIV-1 ribonucleic acid (RNA) undetectable
    - Stable anti-retroviral therapy for more than three months
        - Absence of serious complications associated with HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, or resistant fungal infections, or Kaposi's sarcoma or other neoplasm)

Living donor pancreas transplantation (i.e., partial pancreas transplantation, segmental pancreas transplantation) is considered experimental, investigational or unproven.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Kidney Transplantation

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

CPT®* Codes	Description
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
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

HCPCS Codes	Description
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

Simultaneous Pancreas-Kidney (SPK) Transplantation

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
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

CPT®* Codes	Description
	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
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

HCPCS Codes	Description
S2065	Simultaneous pancreas kidney transplantation
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

Pancreas Transplantation Alone (PTA)

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

HCPCS Codes	Description
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

Pancreas-After-Kidney (PAK) Transplantation

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

HCPCS Codes	Description
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

Considered Experimental/Investigational/Unproven when used to report living donor pancreas transplantation (i.e., partial pancreas transplantation, segmental pancreas transplantation):

CPT®* Codes	Description
48999	Unlisted procedure, pancreas

General Background

KIDNEY

Kidney Failure: Kidney failure means the kidneys no longer work well. With kidney failure, 85-90% of the kidney function is gone. People with kidney failure have stage 5 chronic kidney disease (CKD, also known as end-stage kidney disease or ESKD). The National Kidney Foundation (NKF) states Stage 5 CKD kidney failure is estimated glomerular filtration rate (eGFR) less than 15 for 3 months or more or the individual is on dialysis.

There are two types of treatment for kidney failure: dialysis or transplant.

Transplant is a treatment for kidney failure using a healthy kidney from a living or deceased donor that can help patients live a longer, more normal life than dialysis treatment. On average, a

kidney transplant from a living donor lasts about 15 to 20 years, and a kidney from a deceased donor lasts 8 to 12 years. Some will last longer; others will last less. Most people get a kidney transplant after being on dialysis for some amount of time.

Glomerular Filtration Rate: People with kidney failure have stage 5 chronic kidney disease (CKD, also known as end-stage kidney disease or ESKD). The National Kidney Foundation (NKF) states Stage 5 CKD kidney failure is estimated glomerular filtration rate (eGFR) less than 15 for 3 months or more or the individual is on dialysis.

Estimated glomerular filtration rate (eGFR) is a calculation used to estimate how well the kidneys are filtering certain agents produced by the body. Healthcare providers measure eGFR in milliliters of cleansed blood per minute per body surface (a measurement that reads mL/min/1.73m2). In adults, the normal eGFR number is usually 90-100. That means kidney function is 90-100%. eGFR declines with age, even in people without kidney disease.

Living Donor Kidney Transplantation: An integral part of the nation's organ donation system is the living donor. Living donors can be related or unrelated to the recipient. Living kidney donation eliminates the recipient's need for waiting time on a national waiting list, are often more successful, and can add psychological benefits to both donor and recipient. Nonetheless, the benefit to the recipient of a live-donor organ must outweigh the risks to the donor. In the absence of a living donor, many transplanted kidneys come from deceased (i.e., cadaver) organ donors.

Retransplantation: In general, retransplantation is considered by some to be a controversial procedure, in part due to ethical concerns over the limited supply of organs. A wide range of donor, recipient and other transplant-related factors can influence graft survival. In the event of renal graft failure, renal replacement therapy consists of either dialysis or retransplantation. Although allograft survival is considered good, it is considerably less compared to the primary transplant. Candidates awaiting kidney retransplant are often allosensitized and may be less likely to receive a transplant than primary candidates. As a result, some transplant centers have developed ongoing efforts involving desensitization protocols to prevent antibody-mediated acute rejection. Although desensitization protocols may be considered for deceased donor kidney, protocols are generally attempted with living donation so that antibody response against donor tissue can be monitored; patients proceed to transplant surgery only if antibody levels are low. Authors contend that desensitizing highly sensitive patients improves clinical outcomes (short-term patient and graft survival) however acute antibody-mediated rejection is a barrier in 20-30% of patients and there is no consensus regarding which protocol is ideal.

PANCREAS

The standard treatment for control of blood sugar levels in type I diabetes mellitus (DM) is the use of exogenous insulin; however, this does not entirely restore normal glucose metabolism. Most people who are newly diagnosed with type 2 diabetes are usually treated with a combination of diet, exercise, and an oral medication. Some oral medications (e.g., metformin) improve the body's response to insulin. Other medications cause the body to produce more insulin. Some people will need to add insulin or another injectable medication because their blood sugar levels are not controlled. Using a combination of treatments (oral medication plus insulin) generally means that the person can take a lower dose of insulin, compared with if insulin treatment is used alone.

Pancreas transplantation has been demonstrated to improve the quality of life of people with diabetes, primarily by eliminating acute complications. Pancreas transplantation eliminates the need for exogenous insulin, daily glucose monitoring and many dietary restrictions imposed by diabetes. Additional benefits of pancreas transplantation include the elimination of life-threatening

risks of hypoglycemic unawareness and prevention and reversal of diabetic nephropathy. Pancreas transplantation may be performed:

- alone (i.e., Pancreas Transplantation Alone [PTA]), or
- simultaneously with kidney transplants (i.e., Simultaneous Pancreas-Kidney [SPK]) or
- after a kidney transplant (i.e., Pancreas After Kidney [PAK])

Evidence in the scientific published literature supports pancreas transplantation as an appropriate therapeutic intervention for individuals with diabetes on insulin or who have pancreatic exocrine insufficiency who require or have previously had a kidney transplant. Pancreas transplantation is a well-established and accepted method of treatment for these individuals, particularly the type 1 diabetic. More recently, pancreas transplant has become an accepted method of treatment for type 2 diabetics, with both short-term and long-term outcomes commensurate with type 1 diabetes patients. Gruessner et al. (2017) reported patient, pancreas, and kidney graft survival rates increased significantly over time and reached 95.8, 83.3, and 91.1%, respectively, at 3 years post-transplant for transplants performed between 2009 and 2015.

Living Donor Pancreas Transplantation: The OPTN Policy document (7/25/2024 Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets) does not address living donor pancreas transplant.
Living (partial, segmental) donor pancreas transplantation has been performed in a few centers, including those outside the United States; however, it is not considered widespread in clinical practice. In many cases, the living pancreas donor is a relative of the recipient. In the United States living donor pancreas transplantation has been largely studied at one center, the University of Minnesota. Between January 1, 1994 to May 1, 2013, a total of 46 living-donor segmental pancreas transplants (LDSPTx) including 40 SPK, 2 PAK, and 4 PA were performed at the University of Minnesota (Kirchner, et al., 2016). Kirchner et al. stated that the rate of LDSPTx has significantly decreased over the last few years (on intent) in order to assess donor outcomes and safety prior to actively continuing the living donor (LD) pancreas program. The new onset of diabetes mellitus (DM) requiring oral hypoglycemic management was diagnosed in 7 (15%) donors and insulin-dependent DM in 5 (11%). LD pancreas transplantation (especially SPK) should be offered in carefully selected donor-recipient pairs if metabolic risks for the donor are minimized by careful pre-donation screening and meticulous post-donation follow-up with interventions to prevent significant weight gain. Kirchner et al. concluded that LDSPTx can be performed with good recipient outcomes. The donation is associated with donor morbidity including impaired glucose control. Donor morbidity can be minimized by using risk stratification model and pre-donation counseling on lifestyle modifications post-donation (Kirchner, et al., 2016).

The evidence for living donor pancreas transplantation is limited and primarily in the form of few retrospective reports and patient-registry data (Nagaraju, et al., 2023; Henderson, et al., 2018; Lam, et al., 2017; Kirchner, et al., 2016; Choi, et al., 2016; Sutherland, et al., 2012). Donor and recipient selection criteria for living donor pancreas transplantation have not been clearly defined in the medical literature. Long-term clinical outcomes for the donor and recipient have not been reported. In the short-term, there is limited evidence supporting normalizing insulin production for selected recipients, but concerns remain regarding negative metabolic impact to donors.

Note: For islet cell transplantation, see Coverage Policy 0107 Pancreatic Islet Cell Transplantation.

Retransplantation: For all three types of pancreas transplants, survival rates for a second transplant are lower than for the primary transplant, although an elective retransplant may be considered suitable for a select group of patients. The medical literature suggests in some patients, a retransplant could improve health outcomes after graft loss, although there is

insufficient data regarding health outcomes associated with third and subsequent pancreas transplants to allow strong conclusions.

Contraindications – Kidney and/or Pancreas Transplantation
Although it may vary by transplant center, generally absolute contraindications to kidney transplantation include the following:

- Active infections
- Active malignancy (excluding non-melanoma skin cancers)
- Active substance use disorder (with center-specific policies on marijuana use)
- Reversible kidney failure
- Uncontrolled psychiatric disease
- Documented active and ongoing treatment nonadherence

A significantly shortened life expectancy is generally a contraindication to transplantation. Recipient age alone is not a contraindication to transplantation (Rossi/UpToDate, 2025).

Absolute contraindications for simultaneous pancreas-kidney (SPK) or pancreas after kidney (PAK) transplant that are adopted by most centers include:

- Age >65 years
- Non-insulin-requiring diabetes
- Body mass index (BMI) >35 kg/m2
- Advanced cardiopulmonary disease (ejection fraction below 30 percent, pulmonary artery systolic pressure >50 mmHg, or positive cardiac stress test with uncorrectable coronary artery disease)
- Heavy smoking (>1 pack per day or patients with moderate-to-severe smoking-related morbidities [coronary heart disease, symptomatic or documented cerebrovascular or peripheral vascular disease, chronic obstructive lung disease, history of noncutaneous malignancy])
- Severe peripheral vascular (aorto-iliac) disease
- Moderate to severe dysfunction in other (non-kidney) organ systems (lung, liver, central nervous system [CNS]) including cirrhosis, portal hypertension, advanced chronic obstructive pulmonary disease, dementia, or severe neurologic deficits
- Active malignancy with the exception of nonmelanoma skin cancer or low-grade prostate cancer
- Severe local or systemic infection
- Inadequate psychosocial support and financial resources
- Active substance addiction or abuse
- Major psychiatric illness that cannot be managed sufficiently to enable posttransplant care and safety
- Poor overall functional and performance status (severe deconditioning or malnutrition, frailty, dementia, wheelchair user, need for chronic oxygen therapy)
- Chronic nonhealing wounds
- Projected life expectancy <5 years

Relative contraindications to simultaneous pancreas-kidney (SPK) or pancreas after kidney (PAK) transplantation may also vary depending upon the transplant center (Alhamad/UpToDate, 2023).

Professional Societies/Organizations – Kidney and/or Pancreas Transplantation

United Network for Organ Sharing (UNOS)/ Organ Procurement and Transplantation Network (OPTN): In 1984 the National Organ Transplantation Act directed the Secretary of HHS to

'establish by contract the Organ Procurement and Transplantation Network (OPTN) which shall be a private, non-profit entity that has an expertise in organ procurement and transplantation'. The United Network for Organ Sharing (UNOS) is the current OPTN Contractor. OPTN policies are updated annually and are rules that govern operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S. Policies are made through a collaborative process involving committees, the board of directors and the public.

The UNOS/OPTN Policies (8/1/2025) have established waiting time criteria for Kidney Transplantation depending on the age of the transplant candidate.

8.3.A Waiting Time for Candidates Registered at Age 18 Years or Older
If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following:

1. The candidate's registration date with a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min.
2. The date after registration that a candidate's GFR or measured or estimated CrCl becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

8.3.B Waiting Time for Candidates Registered prior to Age 18
If a kidney candidate is less than 18 years old at the time of registration on the waiting list, then the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered on the waiting list regardless of clinical criteria.
2. The date that the candidate began regularly administered dialysis as an ESRD patient in a hospital based, independent non-hospital based, or home setting.

The UNOS/OPTN Policies for Pancreas Transplant includes the following:

11.2.A Pancreas Registration
Each candidate registered on the pancreas waiting list must meet ONE of the following requirements:

- Be diagnosed with diabetes
- Have pancreatic exocrine insufficiency
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

11.2.B Combined Kidney-Pancreas Registration (i.e., Simultaneous Pancreas-Kidney [SPK])
Each candidate registered on the kidney-pancreas waiting list must

- be diagnosed with diabetes, or
- have pancreatic exocrine insufficiency with renal insufficiency.

11.3.A Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old
To accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate who is less than 18 years old at the time of kidney-pancreas registration does not have to meet the qualifying criteria according to Policy 11.4 B below.

11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old
If a kidney-pancreas candidate is 18 years or older on the date the candidate is registered for a kidney-pancreas, then the candidate begins to accrue waiting time once the candidate has met ALL of the following conditions:

- candidate is registered for a kidney-pancreas.
- candidate qualifies for kidney waiting time according to Policy 8.3: Waiting Time.
- candidate is on insulin.

Once a kidney-pancreas candidate begins to accrue waiting time, the candidate will remain qualified for waiting time.

Kidney Disease Improving Global Outcomes (KDIGO): The KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD) included the following Practice Points:

2.2 Risk prediction in people with CKD

- Practice Point 2.2.3: A 2-year kidney failure risk threshold of >40% can be used to determine the modality education, timing of preparation for kidney replacement therapy (KRT) including vascular access planning or referral for transplantation, in addition to eGFR-based criteria and other clinical considerations

5.3 Team-based integrated care

- Practice Point 5.3.1: Enable access to a patient-centered multidisciplinary care team consisting of dietary counseling, medication management, education, and counseling about different KRT modalities, transplant options, dialysis access surgery, and ethical, psychological, and social care for people with CKD.

5.4 Timing the initiation of dialysis

- Practice Point 5.4.3: Consider planning for preemptive kidney transplantation and/or dialysis access in adults when the GFR is <15–20 ml/min per 1.73 m^2 or risk of KRT is >40% over 2 years.

- Practice Point 5.4.5: Pursue living or deceased donor preemptive kidney transplantation as the treatment of choice for children in whom there is evidence of progressive and irreversible CKD. The eGFR at which pre-emptive transplantation should be undertaken will depend on multiple factors including the age and size of the child and the rate of progression of kidney failure but will usually be between 5–15 ml/min per 1.73 m^2 (KDIGO 2024).

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

A new eGFR equation, the 2021 Chronic Kidney Disease Epidemiology Collaboration (2021 CKD-EPI) equation in which the race variable was removed and the coefficients for the other variables (age, sex, and serum creatinine) were recalibrated, was published (Inker, et al., 2021). Subsequently, the National Kidney Foundation and American Society of Nephrology Task Force

recommended that the 2021 CKD-EPI equation be implemented for eGFR reporting (Delgado, et al., 2022).

The Board of Directors of the Organ Procurement and Transplantation Network (OPTN) unanimously approved a measure to require transplant hospitals to use a race-neutral calculation when estimating a patient's level of kidney function. Effective July 27, 2022, OPTN now requires all transplant hospitals to use race-neutral calculations when estimating a candidate's glomerular filtration rate (GFR) for any purpose covered by OPTN policy.

Effective January 5, 2023, kidney programs are required to assess their waiting lists and correct waiting times for any Black kidney candidates disadvantaged by having their kidney function overestimated due to use of a race-inclusive calculation (OPTN, 2023).

The Board of Directors of the OPTN, at its meeting June 17-18, 2024, approved revisions to the Kidney Donor Profile Index (KDPI), a calculation that estimates the likely length of function of kidneys from a deceased donor according to several criteria. The action will remove two variables – whether the potential donor is African-American/Black and whether the potential donor has tested positive for the hepatitis C virus (HCV). Removing the race and HCV positive variables from the KDPI will better reflect likelihood of graft failure for kidneys from African Americans/Black and HCV positive deceased kidney donors. Currently, kidneys from African American/Black and Hepatitis C (HCV) positive deceased donors have an increased KDPI making them appear less suitable for transplant. The committee proposes refitting the KDPI calculation without race or HCV to better reflect the likelihood of graft failure for kidneys from African American/Black and HCV positive deceased donor kidneys (OPTN, 2024).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	NCD for Pancreas Transplants (260.3)	07/03/2006
NCD		No NCD found for Kidney transplant	
LCD		No LCD found for Kidney or Pancreas transplant	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Appendix

Recommended wait time for SOT candidates with a prior history of breast cancer

Risk/stage	5-year disease-specific survival (%)	Time interval to transplant	Additional considerations
Low risk DCIS Stage I	97 to 99	No wait time necessary*	Hormone receptor negative disease may have a slightly higher risk of recurrence in the first 2 to 3 years.
Intermediate risk Stage II	90 to 99	1 to 2 years NED*	Hormone receptor negative disease may have a slightly higher risk of recurrence in the first 2 to 3 years.
High risk Stage III	66 to 97	3 to 5 years NED*	Hormone receptor negative disease may have a slightly higher risk of recurrence in the first 2 to 3 years. Inflammatory breast cancer likely has a higher risk of recurrence and worse survival.
Prohibitive risk Stage IV	32 to 38	Not an SOT candidate	

Standard oncologic treatments are based on those recommended in the National Comprehensive Cancer Network Breast Cancer guidelines. Breast cancer stages are based on the prognostic stage groups specified in the AJCC's Staging Manual, 8th edition. Anatomic stage groups are not necessarily equivalent to the corresponding prognostic stage groups and should not be applied here.

DCIS: ductal carcinoma in situ; NED: no evidence of disease.

* After completion of all standard treatments. Endocrine therapy does not need to be completed prior to transplant, as this is an oral medication that is fairly well tolerated with few serious side effects and often continues for 5 to 10 years.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of colon cancer

Risk/stage	Recurrence-free survival 5 years (%)	Time interval to transplant	Additional considerations
Low risk ▪ Stage I (T1 or T2, N0, M0)	91	1 year	Low-risk features: ▪ Deficient DNA mismatch repair (as reflected by high levels of MSI) without BRAF mutation High-risk features: ▪ LVI or PNI ▪ Mucinous or signet histology ▪ Poorly differentiated histology ▪ Bowel obstruction ▪ Tumor perforation ▪ <12 lymph nodes examined Tumor deposits considered as N+ disease. Consider chemotherapy prior to transplantation for high-risk stage II disease. Patients with stage III disease should complete chemotherapy.
Low intermediate risk ▪ Stage II (T3, N0, M0)	72	2 years, consider longer if high-risk features present	
High intermediate risk ▪ Stage II (T4, N0, M0) ▪ Stage III (Any T, N+, M0)		3 years, 5 years if high-risk features present	
High risk ▪ Stage IV (Any T, Any N, M+)	13	5 years NED	SOT not recommended prior to 5 years; refer to special consideration regarding resectable CRC metastasis

LVI: lymphovascular invasion; PVI: perineural invasion; MSI: microsatellite instability; CT: computed tomography; CAP: chest, abdomen and pelvis; CEA: carcinoembryonic antigen; NED: no evidence of disease.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of rectal cancer

Risk/stage	Recurrence-free survival 5 years (%)	Time interval to transplant	Additional considerations
Low risk ▪ Stage I (T1 or T2, N0, M0) ▪ Full oncologic resection	85 to 88	1 year, consider 2 years if high-risk features present	Low-risk features: ▪ Deficient DNA mismatch repair (as reflected by high levels of MSI) without BRAF mutation ▪ Upper 1/3 rectum or rectosigmoid High-risk features: ▪ LVI or PNI ▪ Mucinous or signet histology ▪ Poorly differentiated histology ▪ Bowel obstruction ▪ Tumor perforation ▪ <12 lymph nodes examined ▪ Lower 1/3 of rectum ▪ Incomplete mesorectal excision Tumor deposits considered as N+ disease. Patients with stage II and III disease should complete trimodality treatment (chemoradiotherapy, surgery and chemotherapy) unless elimination of one of these is deemed appropriate after multidisciplinary discussion. For patients who have undergone preoperative radiotherapy, response to treatment is highly prognostic. Complete and nearly complete responders have much lower risk for recurrence than those with poor response.
Low intermediate risk ▪ Stage I (T1, N0, M0) ▪ Local excision	78 to 88	2 years	
High intermediate risk ▪ Stage II (T3 or T4, N0, M0) ▪ Stage III (Any T, N+, M0)	70	3 years, 5 years if high-risk features present	
High risk ▪ Stage IV (Any T, Any N, M+)	14	5 years NED	SOT not recommended prior to 5 years; refer to special consideration regarding resectable CRC metastasis

RFS: recurrence-free survival; LVI: lymphovascular invasion; PNI: perineural invasion; MSI: microsatellite instability; CT: computed tomography; CAP: chest, abdomen, and pelvis; CEA: carcinoembryonic antigen; NED: no evidence of disease.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of prostate cancer

Risk/stage	Survival	Time interval to transplant	Additional considerations
Very low risk	<1% risk of mets/death over 15 years	None	Surveillance is strongly recommended
▪ PSA <10 ng/mL			
▪ 3 or fewer cores of Gleason 6 (grade group 1); no greater than 50% of individual core			Extenuating circumstances may require treatment
▪ T1c to T2a			
Low risk	~2 to 3% risk of mets/death over 15 years	None	Surveillance is strongly recommended
▪ PSA <10 ng/mL			
▪ Gleason 6 (not meeting very low-risk criteria)			Extenuating circumstances may require treatment
▪ T1c to T2a			
Low-volume intermediate risk ▪ One of the following criteria: PSA >10 ng/mL, Gleason 7 (grade group 2 or 3), T2b	<5% risk of mets/death over 15 years	If surveillance, no wait time If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years <10%, no wait time	Surveillance or treatment, depending on patient and cancer characteristics
High-volume intermediate risk, high risk, or very high risk ▪ PSA >20 ng/mL or high-volume Gleason 7 or any Gleason 8 to 10, T3	20 to 70% risk of mets/death over 15 years	If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years <10%, no wait time	Treatment
Metastatic castration-sensitive	Median survival ~5 to 6 years	If stable disease for 2 years with prolonged estimated life expectancy, may consider transplant	Best systemic therapy ± local treatment
Metastatic castration-resistant	Median survival 2 to 3 years	Not a SOT candidate	Best systemic therapy

PSA: prostate specific antigen.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of renal cell carcinoma

Stage	Recurrence-free survival 5 years (%)	Time interval to transplant
T1a (≤4 cm), N0, M0	95 to 98	No wait time
T1b (>4 cm to ≤7 cm), N0, M0	91 for FG 1/2	No wait time
	80 to 82 for FG 3/4	1 to 2 years
T2 (7 to 10 cm), N0, M0	80	2 years
T3, N0, M0	43 to 80	Minimum of 2 years, then reassess
T4, N0, M0	28 to 55	Minimum of 2 years, then reassess
Any T, node positive, metastatic disease	0 to 32	Not a candidate (if solitary metastasis +resected, tumor board discussion on candidacy)
Any T with sarcomatoid and/or rhabdoid histologic features	15 to 27	Not a SOT candidate
Collecting duct or medullary RCC	<10	Not a SOT candidate

RCC: renal cell carcinoma; FG: Fuhrman grade (grade 1: inconspicuous nucleoli at ×400 magnification and basophilic, grade 2: clearly visible nucleoli at ×400 magnification and eosinophilic, grade 3: clearly visible nucleoli at ×100 magnification, grade 4: extreme pleomorphism or rhabdoid and/or sarcomatoid morphology).

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of bladder cancer

Bladder cancer history	2-year local recurrence from baseline transurethral resection of bladder tumor (%)	Time interval to transplant
NMIBC low risk*	19	6 months
Intermediate risk¶	39	6 months
High riskΔ	38	2 years
MIBC, postradical cystectomy	25 to 37	2 years
MIBC, postchemoradiation	25 to 30 (10-year)	Not an SOT candidate

NMIBC: nonmuscle invasive bladder cancer; MIBC: muscle invasive bladder cancer.

* Low risk: Solitary, ≤3 cm, low-grade, Ta tumor, absence of carcinoma in situ (CIS).

¶ Intermediate risk: Solitary tumor >3 cm, recurrence within 12 months with low-grade Ta tumor, multifocal low-grade Ta tumor, low-grade T1 tumor, or high-grade tumor <3 cm.

Δ High risk: Any CIS, high-grade Ta tumor >3 cm, high-grade T1 tumor, multifocal high-grade Ta tumor, any recurrent high-grade Ta tumor, CIS, variant histology, lymphovascular invasion, high-grade prostatic urethral involvement, recurrence after BCG intravesical therapy. Although 2-year recurrence rate is lower than intermediate risk, the progression rate to muscle invasion is higher.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of gynecological cancer

5-year recurrence risk	Type and stage	Time interval to transplant
Low risk <5% risk of recurrence	Stage IA/IB, grade 1 to 2 endometrial cancer without lymph-vascular space invasion	No waiting period after completion of primary treatment
	Stage IA/IB/IC grade 1 to 2 epithelial ovarian cancer	
	Stage IA1, IA2 squamous/adenocarcinoma of the cervix	
Intermediate risk 5 to 15% risk of recurrence	Stage I/II endometrial cancer +risk factors*	2 to 3 years after completion of treatment
	Stage IB squamous/adenocarcinoma of the cervix	
High risk >30% risk of recurrence	Serous, clear cell, or carcinosarcoma of uterus (all stages)	5 years after completion of treatment
	Stage III grade 1 to 3 endometrioid cancer of the uterus	
	Stage II/III epithelial ovarian cancer	
	Stage II/III squamous cell/adenocarcinoma cervical cancer	
Very high risk >80% risk of recurrence	Stage IV endometrial cancer (all grades)	Not a SOT candidate
	Recurrent or metastatic endometrial cancer	
	Stage IV epithelial ovarian cancer (any grade)	
	Recurrent ovarian cancer	
	Stage IV squamous cell/adenocarcinoma of the cervix	
	Metastatic or recurrent cervical cancer	

* Risk factors: Older age, lymph-vascular space invasion, grade 2 or 3 endometrioid, deeply invasive tumor.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait time for SOT candidates with a prior history of lung cancer

Stage	Tumor and node	5-year survival (%)	Work-up pre-SOT	Time interval to transplantation	Additional considerations
I	T1aN0	92	PET-CT; consider biopsy post-SBRT	≥3 years	
	T1bN0	83	PET-CT; consider biopsy post-SBRT	≥3 years	
	T1cN0	77	PET-CT; consider biopsy post-SBRT	3 to 5 years	5-year recurrence-free survival is safest
IB	T2aN0	68	PET-CT	5 years	
IIA	T2bN0	60	PET-CT	5 years	
IIB	T3 N0	53	PET-CT	5 years	
IIIA		36	PET-CT	5 years	Special caution with N2 disease
IIIB		26	N/A	N/A	Not an SOT candidate
IIIC		13	N/A	N/A	Not an SOT candidate
IVA		10	N/A	N/A	Not an SOT candidate
IVB		0	N/A	N/A	Not an SOT candidate

SOT: solid organ transplantation; PET-CT: positron emission tomography-computed tomography; SBRT: stereotactic body radiation therapy.

From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.

Recommended wait times pretransplantation for patients with a history of skin cancer before transplantation

Skin malignancy	Appropriate treatment pretransplantation	Wait time before transplantation after treatment
cSCC		
No history of SCC but at risk for development of SCC	Treatment of field disease	No delay necessary
Low risk	Surgical excision with clear margins or Mohs micrographic surgery	No delay necessary
High-risk SCC* (not including perineural invasion)	Surgical excision with clear margins or Mohs micrographic surgery	2 years
High-risk SCC with: ▪ Perineural invasion or ▪ ≥2 Risk factors	Surgical excision with clear margins or Mohs micrographic surgery ± ART	2 to 3 years
High risk with local nodal metastatic disease	Surgical excision with appropriate lymph node dissection plus ART	5 years
Distant metastasis	Refer for oncology opinion	Not eligible for transplantation
MCC		
Local with negative SLN biopsy	Wide local excision ± ART	2 years
Local with nodal metastasis	Wide local excision, lymph node dissection, ART	3 to 5 years
Distant metastasis	Refer for oncology opinion	Not eligible for transplantation
MM		
In situ melanoma	Wide local excision	No wait necessary, follow-up posttransplantation 3 months
Stage Ia melanoma	Wide local excision	2 years
Stage Ib/IIa melanoma	Wide local excision ± sentinel lymph node biopsy	2 to 5 years
Stage IIb/IIc melanoma	Wide local excision + sentinel lymph node biopsy	5 years
Any stage III or IV melanoma	Refer for oncology opinion	Not eligible for transplantation

ART: adjuvant radiation therapy; cSCC: cutaneous squamous cell carcinoma; MCC: Merkel cell carcinoma; MM: malignant melanoma; SCC: squamous cell carcinoma; SLN: sentinel lymph node biopsy.

From: Zwald F, Leitenberger J, Zeitouni N, et al. Recommendations for Solid Organ Transplantation for Transplant Candidates With a Pretransplant Diagnosis of Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma and Melanoma: A Consensus Opinion From the International Transplant Skin Cancer Collaborative (ITSCC). Am J Transplant 2016; 16:407.

Recommended wait time for SOT candidates with a prior history of melanoma

Pathological stage	5-year MS (%)	Appropriate treatment pretransplantation	Time interval to transplant	Additional considerations
In situ	99	Wide local excision	No wait time necessary	Follow-up 3 months post-SOT
Stage IA (T1a)	99	Wide local excision	1 year	
Stage IB (T1b or T2a)	97	Wide local excision plus SLNB	1 year	If positive SLNB at time of diagnosis, imaging as for Stage IIA disease
Stage IIA (T2b or T3a)	94	Wide local excision plus SLNB	1 year	Imaging of the brain, CAP Imaging of the neck for those with head/neck melanoma primary
Stage IIB (T3b or T4a)	87	Wide local excision plus SLNB	2 to 4 years	Imaging as above
Stage IIC (T4b)	82	Wide local excision plus SLNB	2 to 4 years	Imaging as above
Stage IIIA (T1-2a, N1a or 2a)	93	Wide excision plus SLNB plus lymph node dissection	1 ton 2 years	Imaging as above Oncology referral
Stage IIIB (T0-3a and N1a/b/c, N2a/b)	83	Wide excision plus SLNB plus lymph node dissection Adjuvant therapy with CKI	2 to 4 years	Imaging as above Oncology referral
Stage IIIC (T3b-4b and N2b/c-N3b/c)	69	Wide excision plus SLNB plus lymph node dissection Adjuvant therapy with CKI	At least 5 years	Imaging as above Oncology referral (no consensus was possible for this group)
Stage IIID (T4b and N3a-3c)	32	Wide excision plus SLNB plus lymph node dissection Adjuvant therapy with CKI	At least 5 years	Oncology referral (no consensus was possible for this group)
Stage IV	15 to 20	Wide excision plus SLNB plus lymph node dissection Adjuvant therapy with CKI	At least 5 years	Oncology referral (no consensus was possible for this group)

MSS: melanoma-specific survival; SLNB: sentinel lymph node biopsy; CKI: checkpoint inhibitor; CAP: chest, abdomen, and pelvis.

From: Al-Adra DP, Hammel L, Roberts J, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant 2021; 21:475.

Recommended wait time for SOT candidates with a prior history of hematological malignancies

Histology	Survival/relapse data	Time interval to transplant	Additional considerations
Diffuse large B cell lymphoma	Survival is equivalent to age- and sex-matched general population after EFS24 and PFS24 achieved	2 years	
Follicular lymphoma	No added mortality when compared with age- and sex-matched general population after EFS24 achieved	2 years	
Peripheral T cell lymphoma, NOS	23% relapse within 5 years of EFS24, 78% 5-year survival after EFS24 achieved	2 years	
Burkitt lymphoma	0.6% relapse after EFS24 achieved	2 years	
Hodgkin lymphoma	10% relapse at 10 years after EFS24 achieved	2 years	PET scan negative patients after initial treatment have a low rate of relapse
Monoclonal B cell lymphocytosis	N/A	No wait time	
Chronic lymphocytic leukemia	83% 5-year survival untreated	2 to 3 years after treatment	Consider if in remission with no CLL-IPI scores >4

EFS24: event-free survival at 24 months; PFS24: progression-free survival at 24 months; PET: positron emission tomography.

From: Al-Adra DP, Hammel L, Roberts J, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant 2021; 21:475.

Criteria for safe SOT candidates with a prior history of myeloma (top) or amyloidosis (bottom)

Criteria for safe renal transplantation in myeloma
▪ Stringent complete response
• No monoclonal protein in serum or urine by immunofixation
• Normal free light chain ratio
• Bone marrow plasma cells <1% by flow or immunohistochemistry
▪ Performance status 0 or 1
▪ FISH at diagnosis fail to demonstrate deletion (17p), t(4;14), t(14;16)
▪ Hematologic remission >6 months
Criteria for organ transplantation in amyloidosis
▪ Therapeutic response with dFLC of <4 mg/dl
▪ Only one organ involved with amyloidosis
▪ Does not fulfill criteria for symptomatic myeloma
▪ Must be a candidate for stem cell transplantation following organ transplantation

dFLC: difference between involved minus uninvolved serum free light chains.

From: Al-Adra DP, Hammel L, Roberts J, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant 2021; 21:475.

References

1. Al-Adra DP, Hammel L, Roberts J, Woodle ES, Levine D, Mandelbrot D, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant. 2021a Feb;21(2):460-474. (Appendix)

2. Al-Adra DP, Hammel L, Roberts J, Woodle ES, Levine D, Mandelbrot D, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant. 2021b Feb;21(2):475-483. (Appendix)

3. Alhamad T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pretransplant evaluation. In: UpToDate, Brennan DC, Nathan DM (Eds). UpToDate, Waltham, MA. Literature review current through: Jul 2024. Topic last updated: Jan 20, 2023.

4. American Diabetes Association (ADA). Standards of Medical Care in Diabetes. 2025. Accessed August 2025. Available at URL address: https://professional.diabetes.org/standards-of-care

5. American Society of Transplantation. Tools and Specialty Resources. Guidelines. Accessed August 2025. Available at URL address: https://www.myast.org/education/tools-and-specialty-resources/guidelines (none posted)

6. American Society of Transplantation (AST). Key Position Statements. Accessed August 2025. Available at URL address: https://www.myast.org/key-position-statements

7. Boggi U, Vistoli F, Andres A, Arbogast HP, Badet L, et al. First World Consensus Conference on pancreas transplantation: Part II - recommendations. Am J Transplant. 2021 Sep;21 Suppl 3(Suppl 3):17-59.

8. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Aug 2025. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=A&sortBy=title

9. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Aug 2025. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title

10. Choi JY, Jung JH, Kwon H, Shin S, Kim YH, Han DJ. Pancreas Transplantation From Living Donors: A Single Center Experience of 20 Cases. Am J Transplant. 2016 Aug;16(8):2413-20.

11. Delgado C, Baweja M, Burrows NR, Crews DC, Eneanya ND, et al. Reassessing the Inclusion of Race in Diagnosing Kidney Diseases: An Interim Report From the NKF-ASN Task Force. Am J Kidney Dis. 2021 Jul;78(1):103-115.

12. Delgado C, Baweja M, Crews DC, Eneanya ND, Gadegbeku CA, Inker LA, et al. A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease. Am J Kidney Dis. 2022 Feb;79(2):268-288.e1.

13. Giorgakis E, Mathur AK, Chakkera HA, Reddy KS, Moss AA, Singer AL. Solid pancreas transplant: Pushing forward. World J Transplant. 2018 Nov 30;8(7):237-251.

14. Gruessner AC, Laftavi MR, Pankewycz O, Gruessner RWG. Simultaneous Pancreas and Kidney Transplantation-Is It a Treatment Option for Patients With Type 2 Diabetes Mellitus? An Analysis of the International Pancreas Transplant Registry. Curr Diab Rep. 2017 Jun;17(6):44.

15. Henderson ML, DiBrito SR, Thomas AG, Holscher CM, Shaffer AA, et al. Landscape of Living Multiorgan Donation in the United States: A Registry-Based Cohort Study. Transplantation. 2018 Jul;102(7):1148-1155.

16. Inker LA, Eneanya ND, Coresh J, Tighiouart H, Wang D, Chronic Kidney Disease Epidemiology Collaboration, et al. New Creatinine- and Cystatin C-Based Equations to Estimate GFR without Race. N Engl J Med. 2021 Nov 4;385(19):1737-1749.

17. Kidney Disease Improving Global Outcomes (KDIGO) Guidelines. Accessed August 2025. Available at URL address: https://kdigo.org/guidelines/ https://kdigo.org/guidelines/ckd-evaluation-and-management/

18. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024 Apr;105(4S):S117-S314. (See Kidney Disease Improving Global Outcomes [KDIGO] Guidelines.) Available at URL address: https://kdigo.org/guidelines/

19. Kirchner VA, Finger EB, Bellin MD, Dunn TB, Gruessner RW, Hering BJ, et al. Long-term Outcomes for Living Pancreas Donors in the Modern Era. Transplantation. 2016 Jun;100(6):1322-8.

20. Lam NN, Schnitzler MA, Segev DL, Hess GP, Kasiske BL, et al. Diabetes Mellitus in Living Pancreas Donors: Use of Integrated National Registry and Pharmacy Claims Data to Characterize Donation-Related Health Outcomes. Transplantation. 2017 Jun;101(6):1276-1281.

21. National Kidney Foundation. Transplants. Accessed August 2025. Available at URL address: https://www.kidney.org/transplantation (See Kidney Disease Improving Global Outcomes [KDIGO] Guidelines.)

22. National Kidney Foundation. Kidney Topics. Accessed Aug 2025. Available at URL address: https://www.kidney.org/kidney-topics

23. Nagaraju, S, Powelson, JA, Fridell, JA. Techniques of Pancreas Transplantation. In: Jarnagin, WR, Allen, PJ, Chapman, WC, D'Angelica, MI, DeMatteo, RP, Do, RK, Vauthey, J, Blumgart, LH. Blumgart's Surgery of the Live, Biliary Tract, and Pancreas. 7th ed. Philadelphia: Elsevier; 2023. 1844-1852.e2.

24. Organ Procurement and Transplantation Network. Kidney & pancreas. Accessed August 2025. Available at URL address: https://optn.transplant.hrsa.gov/professionals/by-organ/kidney-pancreas/

25. Organ Procurement and Transplantation Network. Policies. Effective 8/1/2025. Accessed August 2025. Available at URL address: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

26. OPTN. News. OPTN Board approves elimination of race-based calculation for transplant candidate listing. June 28, 2022. Accessed August 2025. Available at URL address: https://optn.transplant.hrsa.gov/news/optn-board-approves-elimination-of-race-based-calculation-for-transplant-candidate-listing/

27. OPTN. News. OPTN Board approves exclusion of race, hepatitis C status from estimate of deceased donor kidney function. June 28, 2024. Accessed August 2025. Available at URL address: https://optn.transplant.hrsa.gov/news/optn-board-approves-exclusion-of-race-hepatitis-c-status-from-estimate-of-deceased-donor-kidney-function/

28. OPTN Executive Committee Proposed Strategic Plan 2021-2024. Accessed August 2024. Available at URL address: https://optn.transplant.hrsa.gov/media/4355/2021_2024_optn_strategic_plan_proposal.pdf

29. OPTN Executive Committee Proposed Strategic Plan 2024-2027. Accessed August 2025. Available at URL address: https://optn.transplant.hrsa.gov/media/nwrksrgl/exec_2024-2027-strategic-plan_pcjan24.pdf

30. Rossi AP, Cheng XS. Kidney transplantation in adults: Evaluation of the potential kidney transplant recipient. In: UpToDate, Brennan DC, Vella J (Eds). UpToDate, Waltham, MA. Literature review current through July 2025. Topic last updated July 16, 2024.

31. Sutherland DE, Radosevich D, Gruessner R, Gruessner A, Kandaswamy R. Pushing the envelope: living donor pancreas transplantation. Curr Opin Organ Transplant. 2012 Feb;17(1):106-15.

32. U.S. Department of Health and Human Services. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD). Kidney Disease for Health Professionals. Estimating Glomerular Filtration Rate. Accessed August 2025. Available at URL address: https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/kidney-disease/laboratory-evaluation/glomerular-filtration-rate/estimating

33. U.S. Department of Health and Human Services. Office of Minority Health. (Organ Donation) Accessed August 2025. Available at URL address: https://minorityhealth.hhs.gov/omh/find.aspx (organ donation) https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27

34. Venstrom JM, McBride MA, Rother KI, Hirshberg B, Orchard TJ, Harlan DM. Survival after pancreas transplantation in patients with diabetes and preserved kidney function. JAMA. 2003 Dec 3;290(21):2817-23.

35. Zelnick LR, Leca N, Young B, Bansal N. Association of the Estimated Glomerular Filtration Rate With vs Without a Coefficient for Race With Time to Eligibility for Kidney Transplant. JAMA Netw Open. 2021 Jan 4;4(1):e2034004.

36. Zwald F, Leitenberger J, Zeitouni N, Soon S, Brewer J, et al. Recommendations for Solid Organ Transplantation for Transplant Candidates With a Pretransplant Diagnosis of Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma and Melanoma: A Consensus Opinion From the International Transplant Skin Cancer Collaborative (ITSCC). Am J Transplant. 2016 Feb;16(2):407-13. (Appendix)

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Added policy statements if history of malignancy	10/15/2025
Annual Review	• Removed policy statement for Mechanical preservation machines. Cigna Omnibus Reimbursement Policy R24 addresses donor organ procurement and transport.	10/15/2024
Annual Review	• Updated to new template and formatting standards.	10/15/2023