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Kidney Transplant

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Related Policies (if applicable)
SUR703.001: Organ and Tissue Transplantation (General Donor and Recipient Information)

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Texas ONLY: For policies (IFM, Student, Small Group, Mid-Market, Large Group, fully-insured Municipalities/Counties/Schools, State Employee Plans, PPO, HMO, POS) delivered, issued for delivery, or renewed on or after January 1, 2024, TIC Chapter 1380 (§§ 1380.001 – 1380.003 [SB 1040 Human Organ Transplant]) prohibits coverage of a human organ transplant or post-transplant care if the transplant operation is performed in China or another country known to have participated in forced organ harvesting; or the human organ to be transplanted was procured by a sale or donation originating in China or another country known to have participated in forced organ harvesting. The commissioner of state health services may designate countries who are known to have participated in forced organ harvesting. Forced organ harvesting is defined as the removal of one or more organs from a living person by means of coercion, abduction, deception, fraud, or abuse of power or a position of vulnerability.

Coverage

A kidney transplant alone with either a living or deceased donor in carefully selected candidates **may be considered medically necessary** in:

- Patients age 2 years and older:
  - Evaluation and acceptance by the facility's transplant center committee; **AND** one of the following:
    - Chronic kidney disease (CKD) with calculated creatinine clearance or estimated glomerular filtration rate (eGFR) of less than or equal to 20 ml/min (**SEE NOTE 1**); **OR**
    - Failing kidney transplant allograft with calculated creatinine clearance or eGFR of less than or equal to 20 ml/min; **OR**
    - End-stage renal disease (ESRD) dependent on dialysis.
- Patients age under 2 years:
  - Evaluation and acceptance by the facility's transplant center committee; **AND** one of the following:
    - CKD; **OR**
    - Failing kidney transplant allograft; **OR**
    - ESRD.

Kidney transplant **is considered experimental, investigational and/or unproven** in all other situations.

NOTE 1: Per a joint statement by the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN), race modifiers should not be included in equations to estimate kidney function.

NOTE 2: Refer to SUR703.001, Organ and Tissue Transplantation for general donor and recipient information.

Policy Guidelines

None.

Description

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. (1) Many advances have been made in the last several decades to reduce perioperative complications. Available data support 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 Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS).

Kidney Transplant

In 2022, 42,889 transplants were performed in the United States procured from 36,421 deceased donors and 6,468 living donors. (2) Kidney transplants were the most common procedure with 25,500 transplants performed from both deceased and living donors in 2022. Since 1988, the cumulative number of kidney transplants is 553,905. (3) Of the cumulative total, 67% of the kidneys came from deceased donors and 33% from living donors.

Kidney transplant, using kidneys from deceased or living donors, is an accepted treatment of end-stage renal disease (ESRD). ESRD refers to the inability of the kidneys to perform their functions (i.e., filtering wastes and excess fluids from the blood). ESRD, which is life-threatening, is also known as chronic kidney disease (CKD) stage 5 and is defined as a glomerular filtration rate (GFR) less than 15 mL/min/1.73 m^2. (4) Patients with advanced chronic kidney disease, mainly stage 4 (GFR 15 to 29 mL/min/1.73 m^2) and stage 5 (GFR <15 mL/min/1.73 m^2), should be evaluated for transplant. (5) Some sources, however, define ESRD as stage 6 (non-official designation), which is an addition to the current accepted stages of chronic kidney disease (CKD), as referenced in Table 1 below. Once the estimated glomerular filtration rate (eGFR) declines to less than 30 mL/min per 1.73 m^2 in children less than 12 years of age and the child has stage 4 chronic kidney disease, the child and the family should be prepared for renal replacement therapy (i.e., hemodialysis, peritoneal dialysis, and renal transplantation). (6, 7) Being on dialysis is not a requirement to be considered for kidney transplant. Severe non-compliance and substance abuse serve as contraindications to kidney transplantation but even those could be overcome with clinician support and patient motivation. All kidney transplant candidates receive organ allocation points based on waiting time, age, donor-recipient immune system compatibility, prior living donor status, distance from donor hospital, and survival benefit. (8, 9)

The eGFR is calculated from the results of serum creatinine and the patient's age, body size, and gender. Refer to Table 1 for the stages of CKD with the associated eGFRs for all patients greater than the age of 2 years.

Table 1. Stages of Chronic Kidney Disease (CKD)

Stage	**Description**	**Symptoms**	**eGFR for Greater than 2 Years of Age (mL/min/1.73m^2)**
At Increased Risk	Risk factors for kidney disease (e.g., diabetes, high blood pressure, family history, older age, ethnic group, genetic disease)	No symptoms	More than 90
1	Kidney damage with normal kidney function	Normally no symptoms	90 or higher
2	Kidney damage with mildly reduced kidney function	Normally no symptoms	60 to 89
3a	Moderately reduced kidney function	Normally no symptoms	45 to 59

3b	Moderately reduced kidney function	May start to have symptoms of CKD	30 to 44
4	Severely reduced kidney function	Increasing CKD symptoms and planning for treatment options for next stage	15 to 29
5	Kidney failure, very severely reduced and cannot support the body	This is also called end-stage renal disease (ESRD) or established renal failure – started on treatment options, including dialysis and kidney transplantation	Less than 15

Table Key:
eGFR: estimated glomerular filtration rate;
CKD: chronic kidney disease.

As a result of renal maturation, the eGRF will be considerably lower in children less than 12 years of age than children greater than 12 years of age. For the same conclusion of renal maturation, the stages of CKD cannot be applied to children less than 2 years. (10) Table 2 provides the normal eGFR for infants, toddlers, and children.

Table 2. Normal Glomerular Filtration Rate in Children <12 Years of Age (11)

Age	**Average eGFR (mL/min/1.73m^2)**	**Average eGFR Range (mL/min/1.73m^2)**
2 to 8 days	39	17 to 60
4 to 28 days	47	26 to 68
37 to 95 days	58	30 to 86
1 to 6 months	77	39 to 114
6 to 12 months	103	49 to 157
12 to 19 months	127	62 to 191
2 to 12 years	127	89 to 165

eGFR: estimated glomerular filtration rate.

Creatinine is a marker for eGFR to assess renal function. Increasing creatinine levels signify the inability of the kidney(s) to remove waste from the body. As the levels rise, kidney function decreases. Serum creatinine levels varies in gender, ethnicity, and race. The following are considered within the normal ranges for serum creatinine:

- Adult males: 0.5-1.2 mg/dL.
- Adult females: 0.4-1.1 mg/dL.

- Children (<12 years of age): 0.0-0.7 mg/dL.

Urine creatinine concentrations may vary depending on fluid intake/hydration status. The following are examples of normal ranges for urine creatinine:
- Adult males: 20-25 mg/kg/day (roughly 1575 mg/day for a 70-kg male).
- Adult females: 15-20 mg/kg/day (roughly 1050 mg/day for a 60-kg female).

Contraindications
Potential contraindications to solid organ transplant (subject to the judgment of the transplant center):
- Known current malignancy, including metastatic cancer;
- Recent malignancy with high risk of recurrence;
- History of cancer with a moderate risk of recurrence;
- Systemic disease that could be exacerbated by immunosuppression;
- Untreated systemic infection making immunosuppression unsafe, including chronic infection;
- Other irreversible end-stage diseases not attributed to kidney disease;
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Renal-Specific Criteria
Indications for renal transplant include a creatinine level of greater than 8 mg/dL, or greater than 6 mg/dL in symptomatic diabetic individuals; however, consideration for listing for renal transplant may start well before the creatinine level reaches this point, based on the anticipated time that an individual may spend on the waiting list.

Preemptive Kidney Transplant
Preemptive kidney transplantation is elective transplantation prior to the initiation of chronic dialysis. In general, most patients with late-stage CKD (eGFR less than or equal to 20 mL/min), a failing renal transplant allograft, or ESRD who are suitable candidates for kidney transplant can be considered for preemptive transplantation. (12) While not an absolute contraindication, patients with severe nephrotic syndrome and patients seeking a second kidney transplant after failure of a first transplant within one year may both benefit from a period of time on dialysis.

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.

Rationale

The policy was created in 1990 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through June 14, 2023.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Kidney Transplant

Clinical Context and Therapy Purpose

The purpose of a kidney transplant in individuals who have end-stage renal disease (ESRD) without contraindications to a kidney transplant is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are individuals with ESRD without contraindications to a kidney transplant. ESRD refers to the inability of the kidneys to perform their functions (i.e., filtering wastes and excess fluids from the blood). ESRD, which is life-threatening, is also known as stage 5 chronic renal failure and is defined as a glomerular filtration rate less than 15 mL/min/1.73 m^2. (4)

Interventions

The therapy being considered is kidney transplant from a living or cadaveric donor.

Comparators

The following therapies and practices are currently being used to make decisions about managing ESRD: medical management, including dialysis and medications to control symptoms. Dialysis is an artificial replacement for some kidney functions. Dialysis is used as a supportive measure in patients who do not want kidney transplants or who are not transplant candidates; it can also be used as a temporary measure in patients awaiting a kidney transplant.

Outcomes
The general outcomes of interest are overall survival (OS), elimination of the need for dialysis, and treatment-related adverse events (e.g., immunosuppression, graft failure, surgical complications, infections), with follow-up ranging from 30 days post-transplantation up to 10 years or more. See the Potential Contraindications section for detailed discussion.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Chaudhry et al. (2022) published a systematic review that compared survival for waitlisted patients with kidney failure who received a transplant compared to those who remained on the transplant waitlist. (13) A total of 48 observational studies were included in the systematic review, of which 18 studies were suitable for meta-analysis. Results demonstrated a 55% reduction in the risk of mortality in patients who received a transplant compared to those who remained on dialysis (hazard ratio [HR], 0.45; 95% confidence interval [CI], 0.39 to 0.54; p<.001).

Registry Studies
According to data analysis from the Organ Procurement and Transplantation Network (OPTN), between 2008 and 2015, the 1-year survival of patients undergoing an initial kidney transplant was 97.1% (95% confidence interval [CI], 96.9% to 97.2%). (3) Five-year survival was 86.5% (95% CI, 86.2% to 86.8%).

Krishnan et al. (2015) published a study of 17,681 patients in a U.K. transplant database who received a kidney transplant or were on a list to receive a kidney transplant. (14) Authors found significantly higher 1- and 5-year survival rates in patients who underwent a kidney transplant than in those who remained on dialysis (exact survival rates not reported).

Preemptive Transplant
In a study of 40,000 primary renal transplants in both children and adults from the United

States Renal Data System (USRDS), patients who received a transplant prior to initiation of dialysis had improvements in risk of graft loss and risk of death. For deceased donor kidneys transplanted preemptively, there was a 20% reduction in risk of graft loss (relative risk [RR] 0.75, 95% CI 0.67-0.84), and 16% reduction in risk of death (RR 0.84, 95% CI 0.72-0.99). For live donor kidneys transplanted preemptively, there was a 27% reduction in risk of graft loss (RR 0.73, 95% CI 0.62-0.83) and 31% reduction in risk of death (RR 0.69, 95% CI 0.56-0.85). (15)

A study of 7948 patients in the Dutch National Organ Transplant Registry showed a 10-year survival benefit of patients receiving a preemptive renal transplant (73% survival) versus remaining 3 years on dialysis (45% survival). In addition, the survival benefit in 40-year-old patients receiving a preemptive transplant was approximately 7.5 to 9.9 years. In 70-year-old patients, the survival benefit of those receiving a preemptive transplant was 4.3 to 6 years. (16)

A European study looked at 1113 first renal transplants in children. An association of a lower rate of rejections in the first three years (48 versus 63 percent) was found in patients receiving preemptive transplant. At six years, there was no difference in loss of transplant function. However, there was a trend that favored preemptive transplantation (82 versus 69 percent). (17)

Patients with severe nephrotic syndrome, particularly membranous nephropathy, can have a hypercoagulable state whose etiology is not understood. Abnormalities in coagulation found in patients with nephrotic syndrome include decreased levels of antithrombin III, plasminogen, and protein C and S; increased platelet activation; hyperfibrinogenemia; inhibition of plasminogen activation; and the presence of high-molecular-weight fibrinogen moieties in the circulation. (18-24) This hypercoagulable state can increase the risk of allograft thrombosis. The optimal treatment to decrease nephrotic syndrome and its effects remains unclear. Time on dialysis may help to lower urinary protein losses as residual kidney function declines. While not a contraindication, careful consideration should be given to preemptive transplantation in a patient with severe nephrotic syndrome.

Preemptive kidney transplant after failure of a prior first kidney transplant appears to be beneficial. In a study of 3509 preemptive and 14,075 nonpreemptive second kidney transplant recipients in the U.S. Renal Data System between 1995 and 2007, preemptive recipients had less acute rejection (12% vs. 16%; P<0.0001) and delayed graft function (8% vs. 23%; P<0.0001). Preemptive transplantation was also associated with a lower multivariate adjusted risk of allograft failure from any cause including death (hazard ratio [HR], 0.88; 95% confidence interval [95% CI], 0.81-0.96) and death with a functioning graft (HR [95% CI], 0.76 [0.66-0.87]) but a similar risk of death-censored graft loss (HR [95% CI], 0.98 [0.88-1.08]). The benefits of preemptive transplantation were evident in all patient groups with first transplant survival equal to or more than 1 year; however, a 34% increased risk of death-censored graft loss was observed in preemptive recipients when first transplant survival was less than 1 year. (25) However, in patients with renal transplant failure within 1 year, the optimal timing of transplant and duration of dialysis is unknown and needs further study.

Transplant Stratified by Donor Source

The United Network for Organ Sharing (UNOS) proposed an Expanded Criteria Donor (ECD) approach in 2002 to include brain-dead donors over 60 years or between 50 and 59 years old with 2 or more of the following criteria: serum creatinine level greater than 1.5 mg/dL, death caused by cerebrovascular accident, or history of high blood pressure.

Querard et al. (2016) conducted a systematic review and meta-analysis of studies comparing survival outcomes with ECD versus Standard Criteria Donor (SCD) kidney transplant recipients. (27) Reviewers identified 32 publications, 5 of which adjusted for potential confounding factors. A pooled analysis of 2 studies reporting higher rates of patient-graft failure for ECD kidney recipients found a significantly higher adjusted hazard ratio (HR) for patient-graft survival (HR=1.68; 95% CI; 1.32 to 2.12). Meta-analyses were not conducted for patient survival outcomes; however, 1 study (N=189) found a higher but nonsignificant difference in patient survival with ECD than with SCD (HR=1.97; 95% CI, 0.99 to 3.91) and another (N=13,833) found a significantly increased risk of death with ECD than with SCD (HR=1.25; 95% CI, 1.12 to 1.40).

Pestana (2017) published a retrospective, single-center analysis of kidney transplants performed between 1998 and 2015 at a hospital in Brazil. (26) Of the 11436 transplants analyzed, 31% (n=3614) were performed under SCD, while 14% (n=1618) were performed under ECD. The number of ECD recipients increased over time, from 29 transplants in 1998 to 2000 to 450 transplants from 2013 to 2014. Patient survival with ECD increased from 1998 to 2002 to 2011 to 2014 (from 79.7% to 89.2%, p<.001); a similar increase was noted in patient survival with SCD over the same time periods (from 73.1% to 85.2%, p<.001). The study was limited by reliance on limited registry data.

Several studies have reported on long-term outcomes in live kidney donors. The most appropriate control group to evaluate whether donors have increased risks of morbidity and mortality are individuals who meet the criteria for kidney donation but who did not undergo the procedure. These types of studies have provided mixed findings. For example, Segev et al. (2010) found that donors had an increased mortality risk. (28) The authors analyzed data from a national registry of 80,347 live donors in the U.S. who donated organs between April 1994, and March 2009, and compared their data with data from 9364 participants of the National Health and Nutrition Examination Survey (NHANES) (excluding those with contraindications to kidney donation). There were 25 deaths within 90 days of live kidney donation during the study period. Surgical mortality from live kidney donors was 3.1 per 10,000 donors (95% CI, 2.0 to 4.6) and did not change over times, despite differences in practice and selection. Long-term risk of death was no higher for live donors than for age- and comorbidity-matched NHANES III participants for all patients and also stratified by age, sex, and race.

Candidate Acceptance to Waiting List to Kidney Allocation

According to OPTN/UNOS, for a patient to be placed on a waiting list for kidney allocation, the recipient must meet the following parameters: (9)

"*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 measured or calculated creatinine clearance or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR 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."

"*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."

Potential Contraindications to Kidney Transplant

Human Immunodeficiency Virus (HIV) Infection

Patients infected with HIV may receive organs from HIV-positive donors under approved research protocols through the HIV Organ Policy Equity Act. As of November 2017, 6 hospitals performed 34 such transplants (23 kidney and 11 liver transplants), involving organs from 14 deceased donors. In a prospective, nonrandomized study, Muller et al. (2015) noted that HIV-positive patients transplanted with kidneys from donors testing positive for HIV showed a 5-year survival rate of 74%. (29) Researchers noted that the HIV infection remained well-controlled, and the virus was undetectable in the blood after transplantation.

Locke et al. (2015) examined outcomes in 499 HIV-positive kidney transplant recipients identified in the Scientific Registry of Transplant Recipients (SRTR). (30) Compared with early era transplants (2004-2007), patients transplanted more recently (2008-2011) had a significantly lower risk of death (HR=0.59; 95% CI, 0.39 to 0.90). The 5-year patient survival rate was 78.2% for patients transplanted in the early era and 85.8% for more recent transplants. In another study, Locke et al. (2015) compared outcomes in 467 adult kidney transplant recipients with 4670 HIV-negative controls, matched on demographic characteristics. (31) Compared with HIV-negative controls, survival among HIV-positive transplant recipients was similar at 5 years post-transplant (83.5% versus 86.2%, p=.06). At 10 years, HIV-positive transplant recipients had a significantly lower survival rate (51.6%) than HIV-negative patients (72.1%; p<.001). The lower 10-year survival rate was likely due to HIV and hepatitis C virus (HCV) coinfection; survival rates at 10 years in HIV-monoinfected patients and HIV-negative patients were similar (88.7% versus 89.1%, p=.50). Locke et al. (2017) found significantly lower 5-year mortality rates in HIV-infected patients with ESRD who had kidney transplants compared with continued dialysis (adjusted relative risk [RR], 0.21; 95% CI, 0.10 to 0.42; p<.001). (32)

In addition, Sawinski et al. (2015) analyzed survival outcomes in patients infected with HIV,

HCV, or HIV plus HCV. (33) The analysis included 492 HIV-infected patients, 5605 HCV-infected patients, 147 coinfected patients, and 117,791 noninfected patients. In a multivariate analysis, compared with noninfected patients, HIV-infected patients did not have an increased risk of death (HR=0.90; 95% CI, 0.66 to 1.24). However, HCV infection (HR=1.44; 95% CI, 1.33 to 1.56) and HIV and HCV coinfection (HR=2.26; 95% CI, 1.45 to 3.52) were both significantly associated with an increased risk of death.

Zheng et al. (2019) performed a meta-analysis of 27 cohort studies, accounting for 1670 cases, to analyze various outcomes among HIV-positive patients who underwent kidney transplantation. (34) The results revealed 97% (95% CI, 95% to 98%) survival at 1 year and 94% (95% CI, 90% to 97%) survival at 3 years. Other outcomes comprised 91% (95% CI, 88% to 94%) graft survival at 1 year, 81% (95% CI, 74% to 87%) graft survival at 3 years, 33% (95% CI, 28% to 38%) with acute rejections at 1 year, and 41% (95% CI, 34% to 50%) with infectious complications at 1 year.

Current OPTN policy permits HIV-positive transplant candidates. (9)

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney transplantation in patients with HIV disease. (35) These criteria may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy;
- Cluster of differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months;
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months;
- No opportunistic infections for at least 6 months;
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

Hepatitis C Infection

A meta-analysis by Fabrizi et al. (2014) identified 18 observational studies comparing kidney transplant outcomes in patients with and without HCV infection. (36) The studies included 133,350 transplant recipients. In an adjusted analysis, the risk of all-cause mortality was significantly higher in HCV-positive versus HCV-negative patients (RR=1.85; 95% CI, 1.49 to 2.31). Risks were elevated in various study subgroups examined by investigators. When the analysis was limited to the 4 studies from the U.S., the adjusted RR was 1.29 (95% CI, 1.15 to 1.44). In an analysis of 10 studies published since 2000, the RR was 1.84 (95% CI, 1.45 to 2.34). An analysis of disease-specific mortality suggested that at least part of the increased risk in mortality among HCV-positive individuals must have been due to chronic liver disease. In a meta-analysis of 9 studies, the risk of liver disease-related mortality was considerably elevated in patients infected with HCV than in those uninfected (odds ratio [OR], 11.6; 95% CI, 5.54 to 24.4).

In the analysis by Sawinski et al. (2015), described above, HCV infection was associated with an increased risk of mortality in kidney transplant patients compared with noninfected patients.

(33)

Obesity

Several studies have found that obese kidney transplant patients have improved outcomes compared with patients on a waiting list matched by body mass index (BMI). Study results on whether morbid obesity is associated with an increased risk of adverse events after kidney transplant are conflicting.

In an analysis of kidney transplant data from the U.K., Krishnan et al. (2015) reported on BMI data for 13,536 patients. (14) They devised several BMI categories (i.e., <18.5 kg/m^2, 18.5 to <25 kg/m^2, 25 to <30 kg/m^2, 30 to <35 kg/m^2, and 35 to <40 kg/m^2). For each BMI category, patient survival was significantly higher in those who underwent kidney transplants compared with those who remained on a waiting list. In a similar analysis of U.S. data, Gill et al. (2013) noted that the risk of mortality at 1 year was significantly lower in patients who underwent transplantation than in those who remained on the waiting list for all BMI categories. (37) For example, the risk was lower for patients with a BMI of at least 40 kg/m^2 who received organs from donors who met standard criteria (HR=0.52; 95 CI, 0.37 to 0.72) and for patients with BMI 35 to 39 kg/m^2 who received organs from SCD donors (HR=0.34; 95% CI, 0.26 to 0.46).

Pieloch et al. (2014) retrospectively reviewed data from the OPTN database. (38) The sample included 6055 morbidly obese patients (i.e., BMI, 35 to 40 kg/m^2) and 24,077 normal-weight individuals who underwent kidney transplant between 2001 and 2006. After controlling for potentially confounding factors, the overall 3-year patient mortality did not differ significantly between obese and normal-weight patients (HR=1.03; 95% CI, 0.96 to 1.12). Similar results were found for 3-year graft failure (HR=1.04; 95% CI, 0.98 to 1.11). In subgroup analyses, obese patients who were non-dialysis-dependent, nondiabetic, younger, receiving living donor transplants, and needing no assistance with daily living activities had significantly lower 3-year mortality rates than normal-weight individuals. For example, the odds ratio for mortality between nondiabetic obese and normal-weight patients was 0.53 (95% CI, 0.44 to 0.63).

A multivariate analysis of the effect of obesity on transplant outcomes by Kwan et al. (2016) included 191,091 patients from the SRTR database. (39) Covariates in the analysis included age, sex, graft type, ethnicity, diabetes, peripheral vascular disease, dialysis time, and time period of transplantation. Multivariate regression analysis indicated that obese patients had a significantly increased risk of adverse transplant outcomes including delayed graft function, urine protein, acute rejection, and graft failure (p<.001 for all outcomes). The risk of adverse outcomes of obesity increased with increasing BMI (e.g., see Table 3), and was independent of the effect of diabetes.

Table 3. Hazard Ratio of Graft Failure Relative to a Body Mass Index of 18.5 to 24.9 kg/m^2

Body Mass Index, kg/m^2	Hazard Ratio	95% Confidence Interval	p
25 to 29.9	1.015	0.983 to 1.047	.416
30 to 34.9	1.104	1.065 to 1.145	<.001

35 to 39.9	1.216	1.158 to 1.276	<.001
40+	1.248	1.156 to 1.348	<.001

Type 2 Diabetes

Kervinen et al. (2018) looked at the probability of receiving renal transplantation and survival after transplantation for patients with type 2 diabetes mellitus (T2DM). (40) Using the Finnish Registry for Kidney Diseases, which included 5419 patients between the years 2000 and 2010, 1065 individuals with T2DM were identified, of which 105 received a kidney transplant during follow-up. The relative probability of renal transplantation was 0.25 (95% CI 0.20 to 0.30, p<.001) for T2DM patients compared with non-diabetic patients. Survival probabilities at 5 years after transplantation were 88% for T2DM and 93% for non-diabetic patients (adjusted HR for death 1.39, 95% CI 0.82 to 2.35, p=.227). The limitations of this study were the relatively small number of T2DM patients receiving kidney transplantation and almost all of these were from deceased donors. Also, the transplantation criteria for T2DM patients in Finland may give better survival rates in the study.

Lim et al. (2017) evaluated all-cause mortality following kidney transplantation in patients with T2DM from the Australia and New Zealand Dialysis and Transplant (ANZDT) Registry. (41) Of 10,714 transplant recipients during the study period, 985 (9%) had T2DM. The 10-year unadjusted OS in patients with an intact graft was 53% for individuals who had diabetes compared with 83% for transplant recipients who did not. The adjusted HR for all-cause mortality in patients with diabetes was 1.60 (95% CI, 1.37 to 1.86; p<.001), with the excess risk of death attributable to both cardiovascular disease and infection. Graft survival rates at 1, 5, and 10 years were 94%, 85%, and 70% in patients with diabetes compared with 95%, 89%, and 78% in transplant recipients without diabetes (p<.001), respectively.

Section Summary: Kidney Transplant

A large number of kidney transplants have been performed worldwide. Available data have demonstrated reasonably high survival rates after kidney transplant for appropriately selected patients and significantly higher survival rates for patients undergoing kidney transplant compared with those who remained on a waiting list. HIV infection has not been found to increase the risk of adverse events after kidney transplantation. Obesity and T2DM may increase the risk of adverse outcomes, and some data have suggested that kidney transplant recipients with HCV have worse outcomes than those without hepatitis C infection; however, data have not shown that patients with these conditions do not benefit from kidney transplants.

Kidney Retransplant

Clinical Context and Therapy Purpose

The purpose of kidney retransplants in individuals who have a failed kidney transplant without contraindications to another kidney transplant is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with a failed kidney transplant without contraindications to another kidney transplant.

Interventions
The therapy being considered is kidney retransplant from a living or cadaveric donor.

Comparators
The following therapies and practices are currently being used to make decisions about managing patients whose kidney transplant has failed: medical management including dialysis, self-care, and medications, including dietary supplements and diuretics.

Outcomes
The general outcomes of interest are OS, elimination of the need for dialysis, and treatment-related adverse events (e.g., immunosuppression, graft failure, surgical complications, infections), with follow-up ranging from immediate postsurgery to 30 days post-transplantation and long-term follow-up out to 10 years or more. See the Potential Contraindications section for detailed discussion.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Case Series
Barocci et al. (2009) in Italy reported on long-term survival after kidney retransplantation. (42) There were 100 (0.8%) second transplants of 1302 kidney transplants performed at a single center between 1983 and 2007. Among the second kidney recipients, 1-, 5-, and 10-year patient survival rates were 100%, 96%, and 92%, respectively. Graft survival rates at 1, 5, and 10 years were 85%, 72%, and 53%, respectively.

Registry Studies
Kainz et al. (2022) investigated the association of time on waitlist with survival in patients who received a second transplant versus those who remained on the waitlist. (43) A total of 2346 patients from the Austrian Dialysis and Transplant Registry and Eurotransplant were retrospectively analyzed. Results demonstrated that retransplantation improved survival at 10 years of follow-up compared with remaining on the waitlist (HR for mortality, 0.73; 95% CI, 0.53 to 0.95). For patients with a waitlist time for retransplantation of <1 and 8 years after first graft

loss, the mean survival time differences at 10 years were 8.0 life months gained (95% CI, 1.9 to 14.0) and 0.1 life months gained (95% CI, -14.3 to 15.2), respectively.

According to data analysis from the OPTN between 2008 and 2015, the 1-year survival rate of patients undergoing a repeat kidney transplant was 97.2% (95% CI, 96.8% to 97.5%). (3) The 5-year patient survival rate after a repeat kidney transplant was 88.2% (95% CI, 87.4% to 88.9%).

Children

Gupta et al. (2015) retrospectively analyzed OPTN data, focusing on patients who had an initial kidney transplant as children. (44) A total of 2281 patients were identified who had their first transplant when they were younger than 18 years and a second kidney transplant at any age. In multivariate analysis, length of first graft survival and age at second graft were significantly associated with second graft survival. Specifically, the first graft survival time of more than 5 years was associated with better second graft survival. However, patients who were between 15 and 20 years old at second transplant were at increased risk of second kidney graft failure compared with patients in other age groups.

Potential Contraindications to Kidney Retransplant

HIV Infection

Shelton et al. (2017) evaluated outcomes in HIV-infected patients undergoing kidney retransplantation. (45) In adjusted survival analysis, HIV-infected retransplant patients had a significantly increased risk of death compared with HIV-negative patients (HR=3.11; 95% CI, 1.82 to 5.34). Other factors significantly associated with an increased risk of death after kidney retransplantation included recipient infection with HCV (HR=1.77; 95% CI, 1.32 to 2.38) and grafts from older donors (HR=1.01; 95 CI, 1.00 to 1.02). The analysis included only 22 HIV-infected patients, which is too small to draw conclusions about the appropriateness of kidney retransplantation in HIV-infected individuals.

Other contraindications are discussed in the section on initial kidney transplants.

Section Summary: Kidney Retransplant

Data have demonstrated reasonably high survival rates after kidney retransplant for appropriately selected patients (e.g., 5-year survival rates ranging from 87% to 96%).

Summary of Evidence

For individuals who have end-stage renal disease (ESRD) without contraindications to kidney transplant who receive a kidney transplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data from large registries have demonstrated reasonably high survival rates after kidney transplant for appropriately selected patients and significantly higher survival rates for patients undergoing kidney transplant compared with those who remained on a waiting list. Kidney transplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or in whom post-transplantation care is expected to significantly worsen comorbid conditions. The

evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a failed kidney transplant without contraindications to kidney transplant who receive a kidney retransplant from a living donor or deceased (cadaveric) donor, the evidence includes registry data and case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data have demonstrated reasonably high survival rates after kidney retransplant (e.g., 5-year survival rates ranging from 87% to 96%) for appropriately selected patients. Kidney retransplantation is contraindicated for patients for whom the procedure is expected to be futile due to comorbid disease or for whom post-transplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Society of Transplant Surgeons (ASTS) et al.

In 2011, the American Society of Transplant Surgeons, the American Society of Transplantation, the Association of Organ Procurement Organizations, and the United Network for Organ Sharing issued a joint position statement recommending modifications to the National Organ Transplant Act of 1984. (46) The joint recommendation stated that the potential pool of organs from HIV-infected donors should be explored. With modern antiretroviral therapy, the use of these previously banned organs would open an additional pool of donors to HIV-infected recipients. The increased pool of donors has the potential to shorten waiting times for organs and decrease the number of waiting list deaths. The organs from HIV-infected deceased donors would be used for transplant only with patients already infected with HIV. In 2013, the HIV Organ Policy Equity Act permitted the use of this group of organ donors.

Medicare National Coverage

The Medicare Benefit Policy Manual includes a chapter on end-stage renal disease (ESRD). (47) A section on identifying candidates for transplantation (140.1) states:

"After a patient is diagnosed as having ESRD, the physician should determine if the patient is suitable for transplantation. If the patient is a suitable transplant candidate, a live donor transplant is considered first because of the high success rate in comparison to a cadaveric transplant. Whether one or multiple potential donors are available, the following sections provide a general description of the usual course of events in preparation for a live-donor transplant."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date

NCT04182607	Donor Outcomes Following Hand-Assisted And Robotic Living Donor Nephrectomy: A Retrospective Review	240	Nov 2022
NCT03500315	HOPE in Action Prospective Multicenter, Clinical Trial of Deceased HIVD+ Kidney Transplants for HIV+ Recipients	160	Sept 2023

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	50300, 50320, 50323, 50325, 50327, 50328, 50329, 50340, 50360, 50365, 50370, 50547
HCPCS Codes	S2152

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2024	Reviewed. No changes.
02/01/2024	Document updated with literature review. Coverage unchanged. Added reference 12; others updated.
01/01/2023	Document updated with literature review. Coverage unchanged. References 1, 2, 5, 8, 12, 33 and 42 were added; some updated and others removed.
10/15/2021	Reviewed. No changes.
10/01/2020	Document updated with literature review. The following changes were made to Coverage: 1) The word cadaver was replaced with deceased and the following criteria was added to the medically necessary coverage statement: Patients age 2 years and older with: Chronic Kidney Disease (CKD) with calculated creatinine clearance or estimated glomerular filtration rate (eGFR) of less than or equal to 20 ml/min; OR Failing kidney transplant allograft with

	calculated creatinine clearance or eGFR of less than or equal to 20 ml/min; OR and Patients age under 2 years with: CKD; OR Failing kidney transplant allograft; OR 2) The medically necessary statement for kidney retransplant was removed. References 3, 8-18, 22, 27-28, and 33 were added and some references removed.
05/15/2018	Document updated with literature review. Simultaneous Liver-Kidney Transplant removed from entire policy, including references 23-30. This topic is now addressed on SUR703.008, Liver Transplant and Combined Liver-Kidney Transplant. Title changed from Kidney Transplant, Including Simultaneous Liver-Kidney Transplant. References 14-15 added.
11/17/2017	Document updated with literature review. The kidney transplant alone coverage statement changed to the following: "A kidney transplant alone with either a living or cadaver donor may be considered medically necessary for carefully selected candidates with end-stage renal disease (ESRD) who have been evaluated and accepted by the facility's transplant center committee." Title changed from Kidney Transplant.
11/01/2017	Document updated with literature review. The following was added to kidney transplant alone criteria: "stage 5 with a glomerular filtration rate (GFR) of <15mL/min/1.732 and creatinine of >8 mg/dL or >6 mg/dL in symptomatic diabetic patients." The following coverage statement was added: "A simultaneous (or combined) liver-kidney transplant (SLK) may be considered medically necessary for carefully selected candidates with end-stage liver failure/disease (ESLD)" when meeting specific criteria.
11/01/2016	Reviewed. No changes.
11/01/2015	Document updated with literature review. Coverage unchanged.
11/15/2014	Reviewed. No changes.
12/01/2013	Document updated with literature review. The following was added to Coverage: Kidney retransplant after a failed primary kidney transplant may be considered medically necessary. CPT/HCPCS code(s) updated
06/01/2008	Revised/updated entire document; this policy is no longer scheduled for routine literature and update
01/23/2004	Revised/updated entire document
11/01/1999	Revised/updated entire document
05/01/1996	Medical policy number changed
04/01/1996	Revised/updated entire document
01/01/1992	Revised/updated entire document
05/01/1990	New medical document