Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for a kidney transplant when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Kidney transplants with either a living or cadaver donor are considered medically necessary for carefully selected candidates with end-stage renal disease.

Etiologies of end-stage renal disease include, but are not limited to any of the following conditions associated with end-stage renal disease:

- Obstructive and reflux uropathy unspecified
- Systemic lupus erythematosus unspecified
- Systemic lupus erythematosus
- Polyarteritis nodosa and related conditions
- Wegner’s granulomatosis
- Acute kidney failure with acute cortical necrosis
- Allergic purpura (includes Henoch-Schönlein purpura)
- Hemolytic-uremic syndrome
- Acute kidney failure with tubular necrosis
- Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
- Renal sclerosis NOS
- Ischemia and infarction of kidney (includes renal artery occlusion)
- Embolism and thrombosis of renal vein
- Chronic tubule-interstitial nephritis unspecified
- Unspecified nephritic syndrome unspecified code range (includes focal glomerulosclerosis, glomerulonephritis and nephritis)
- Chronic nephritic syndrome code range
- Recurrent and persistent hematuria with other morphologic changes (includes IgA nephropathy)
- Hypersensitivity angiitis (includes antiglomerular basement membrane [anti-GBM] disease)
Kidney Transplant 7.03.01

- Poisoning by adverse effect of and underdosing of other primarily systemic and hematologic agents code range
- Polycystic kidney disease code range
- Medullary cystic kidney
- Disorders of calcium metabolism code range (includes nephrocalcinosis)
- Gout due to renal impairment code range
- Amyloidosis code range
- Fabry (-Anderson) disease
- Disorders of glycoprotein metabolism code range
- Disorders of ornithine metabolism
- Other specified disorders of carbohydrate metabolism
- Unspecified disorders of carbohydrate metabolism
- Other congenital malformations of the kidney code range Q61.9 Cystic kidney disease unspecified
- Renal agenesis and other defects code range
- Malignant neoplasm of kidney, except renal pelvis (includes renal cell carcinoma and Wilms tumor)
- Multiple myeloma remission code range
- Tuberous sclerosis
- Injury of kidney code range

Kidney retransplant after a failed primary kidney transplant may be considered **medically necessary**.

**When Policy Topic is not covered**
Kidney transplant is considered **investigational** in all other situations.

**Considerations**
Kidney transplants should be considered for coverage under the Transplant Benefit:

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

HIV-positive patients who meet the following criteria, as stated in the 2001 guidelines of the American Society of Transplantation, could be considered candidates for kidney transplantation:
- CD4 count >200 cells per cubic millimeter for >6 months
HIV-1 RNA undetectable
On stable anti-retroviral therapy >3 months
No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidiosis mycosis, resistant fungal infections, Kaposi’s sarcoma, or other neoplasm), and
Meeting all other criteria for transplantation.

Indications for renal transplant include a creatinine level of greater than 8 mg/dL, or greater than 6 mg/dL in symptomatic diabetic patients. However, consideration for listing for renal transplant may start well before the creatinine level reaches this point, based on the anticipated time that a patient may spend on the waiting list.

Transplant Benefit
Transplant requests are generally reviewed by the Plan medical director or his or her designee. Only those patients accepted for transplantation by an approved transplantation center and actively listed for transplant should be considered for precertification or prior approval. Guidelines should be followed for transplant network or consortia, if applicable.

Kidney transplants should be considered for coverage under the transplant benefit.

What is covered under the scope of the human organ transplant (HOT) benefit needs to be considered. Typically, the following are covered under the HOT benefit:

- hospitalization of the recipient and living donor for medically recognized transplants from a donor to a transplant recipient;
- evaluation tests requiring hospitalization to determine the suitability of both potential and actual donors, when such tests cannot be safely and effectively performed on an outpatient basis;
- hospital room, board, and general nursing in semi-private rooms;
- special care units, such as coronary and intensive care;
- hospital ancillary services;
- physicians’ services for surgery, technical assistance, administration of anesthetics, and medical care;
- acquisition, preparation, transportation, and storage of organ;
- diagnostic services;
- drugs that require a prescription by federal law.

Expenses incurred in the evaluation and procurement of organs and tissues are benefits when billed by the hospital. Included in these expenses may be specific charges for participation with registries for organ procurement, operating rooms, supplies, use of hospital equipment, and transportation of the tissue or organ to be evaluated.

Administration of products with a specific transplant benefit needs to be defined as to:
• when the benefit begins (at the time of admission for the transplant or once the patient is determined eligible for a transplant, which may include tests or office visits prior to transplant);
• when the benefit ends (at the time of discharge from the hospital or at the end of required follow-up, including the immunosuppressive drugs administered on an outpatient basis).

Coverage usually is not provided for:
• HOT services for which the cost is covered/funded by governmental, foundational, or charitable grants;
• organs sold rather than donated to the recipient;
• an artificial organ.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>▪ With end-stage renal disease</td>
<td>▪ Kidney transplant from a living donor or deceased (cadaveric) donor</td>
<td>▪ Medical management ▪ Dialysis</td>
<td>▪ Overall survival ▪ Morbid events</td>
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<td>without contraindications to</td>
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<td>▪ Treatment-related mortality ▪ Treatment-related morbidity</td>
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<tr>
<td>kidney transplant</td>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>▪ With a failed kidney transplant</td>
<td>▪ Kidney retransplant from a living donor or deceased (cadaveric) donor</td>
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</tr>
<tr>
<td>kidney transplant</td>
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</tbody>
</table>

A kidney transplant involves the surgical removal of a kidney from a cadaver, living-related, or living-unrelated donor and transplantation into the recipient.

For individuals who have 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 posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful 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 (eg, 5-year survival rates ranging from 87% to 96%) for appropriately selected patients. Kidney retransplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Background**

End-stage renal disease (ESRD) refers to the inability of the kidneys to perform their functions (ie, 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 (GFR) less than 15 mL/min/1.73 m$^2$. 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, and can also be used as a temporary measure in patients awaiting kidney transplant.

Kidney transplant, using kidneys from deceased or living donors, is an accepted treatment of ESRD. Based on data from the Organ Procurement and Transplantation Network, between 1998 and October 2016, 401,913 kidney transplants had been performed in the United States. Of these, 66% of the kidneys came from deceased donors and 34% from living donors.

Combined kidney and pancreas transplants and management of acute rejection of kidney transplant using either intravenous immunoglobulin or plasmapheresis are discussed in separate evidence reviews.

**REGULATORY STATUS**

Kidney transplant is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

**Rationale**

This evidence review was originally created in December 1995 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was conducted through October 25, 2016.

**KIDNEY TRANSPLANT**

**Survival**
According to analysis of data from the Organ Procurement and Transplantation Network (OPTN), between 2008 and 2015, the 1-year survival of patients undergoing an initial kidney transplant was 97.0% (95% confidence interval [CI], 96.8% to 97.1%). Five-year survival was 85.8% (95% CI, 85.5% to 86.1%).

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

Organ Donation
The United Network for Organ Sharing (UNOS) proposed an Expanded Criteria Donor (ECD) approach in 2002 to include brain-dead donors over 60 years old and 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. In 2016, Querard et al conducted a systematic review and meta-analysis of studies comparing survival outcomes with ECD versus Standard Criteria Donor (SCD) kidney transplant recipients. 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).

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. Studies of this type have had mixed findings. For example, Segev et al did not find that donors had an increased mortality risk. The authors analyzed data from a national registry of 80,347 live donors in the United States who donated organs between April 1, 1994, and March 31, 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 donation 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.

Potential Contraindications to Kidney Transplant

HIV Infection
In 2001, the American Society of Transplantation proposed that HIV-positive patients who met the following criteria could be considered candidates for kidney transplantation. (6) (These criteria may be extrapolated to other organs.)

- CD4 count greater than 200 cells per cubic millimeter for more than 6 months
- Undetectable HIV-1 RNA
- On stable anti-retroviral therapy for more than 3 months
- No other complications from AIDS (eg, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi sarcoma, or other neoplasm)
- Meeting all other criteria for transplantation.

Several studies have evaluated outcomes of kidney transplantation in HIV-positive patients. In 2015, Locke et al examined outcomes in 499 HIV-positive kidney transplant recipients identified in the Scientific Registry of Transplant Recipients (SRTR). (7) 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). Five-year patient survival was 78.2% for patients transplanted in the early era and 85.8% for more recent transplants. In another study, Locke et al compared outcomes in 467 adult kidney transplant recipients and 4670 HIV-negative controls, matched on demographic characteristics. (8) Compared with HIV-negative controls, survival among HIV-positive transplant recipients was similar at 5 years posttransplant (83.5% vs 86.2%, p=0.06). At 10 years, HIV-positive transplant recipients had a significantly lower survival rate (51.6%) than HIV-negative patients (72.1%; p<0.001). 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% vs 89.1%, p=0.50). In a 2016 analysis, Locke et al found a significantly lower 5-year mortality rates in HIV-infected patients with end-stage renal disease who had kidney transplants compared with continued dialysis (adjusted relative risk [RR], 0.21; 95% CI, 0.10 to 0.42; p<0.001). (9)

In addition, in 2015, Sawinski et al analyzed survival outcomes in patients infected with HIV, HCV, or HIV and HCV. (10) Analysis included 492 HIV-infected patients, 5605 HCV-infected patients, 147 dually infected 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.

**Hepatitis C Infection**

A 2014 meta-analysis by Fabrizi et al identified 18 observational studies comparing kidney transplant outcomes in patients with and without HCV infection. (11) 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 United States, the adjusted relative risk was 1.29 (95% CI, 1.15 to 1.44). In an analysis of 10 studies published since 2000, relative risk 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 of 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 highly elevated in patients infected with HCV versus uninfected patients (odds ratio [OR], 11.6; 95% CI, 5.54 to 24.4).

In the analysis by Sawinski (described above), HCV infection was associated with an increased risk of mortality in kidney transplant patients compared with noninfected patients.(10)

**Obesity**

Several studies have found that morbid obesity is not associated with an increased risk of adverse outcomes after kidney transplant. In a 2015 analysis of kidney transplant data from the U.K., body mass index (BMI) data were available for 13,536 patients.(3) Authors devised several BMI categories (ie, <18.5 kg/m², 18.5 to <25 kg/m², 25 to <30 kg/m², 30 to <35 kg/m², and 35 to <40 kg/m²). 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, published by Gil et al in 2013, 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.(12) For example, the risk was lower for patients with a BMI of at least 40 kg/m² 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/m² who received organs from SCD donors (HR=0.34; 95% CI, 0.26 to 0.46).

In 2014, Pieloch et al retrospectively reviewed data from the OPTN database.(13) The sample included 6055 morbidly obese patients (ie, BMI, 35-40 kg/m²) 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 nondialysis dependent, nondiabetic, younger, received living-donor transplants, and needed 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).

**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 and obesity have not been found to increase the risk of adverse events after kidney transplantation. 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 hepatitis C infection do not benefit from kidney transplants.

KIDNEY RETRANSPANT

Survival
According to analysis of data from the OPTN between 2008 and 2015, the 1-year survival of patients undergoing a repeat kidney transplant was 97.1% (95% CI, 96.7% to 97.5%). Five-year patient survival after a repeat kidney transplant was 87.6% (95% CI, 86.8% to 88.4%).(2)

In 2015, Gupta et al retrospectively analyzed OPTN data, focusing on patients who had an initial kidney transplant as children.(14) 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, first graft survival time of more than 5 years was associated with better second graft survival. Moreover, 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.

In 2009, Barocci et al in Italy reported on long-term survival after kidney retransplantation.(15) 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.

In 2016, Shelton et al evaluated outcomes in HIV-infected patients undergoing kidney retransplantation.(16) In an 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 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.

Section Summary: Kidney Retransplant
Data have demonstrated reasonably high survival rates after kidney retransplant for appropriately selected patients (eg, 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 posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful 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 (eg, 5-year survival rates ranging from 87% to 96%) for appropriately selected patients. Kidney retransplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

European Renal Best Practice
In 2016, the European Renal Best Practice published guidance on managing older patients (age >65 years) with chronic kidney disease stage 3b or higher (estimated glomerular filtration rate [eGFR] <45 mL/min/1.73 m²).(17) One of the clinical questions in the guidance involved the criteria and appropriateness of transplantation in older patients with end-stage renal failure. Because older patients are often excluded from trials, evidence is limited and the panel issued a separate narrative on the topic.(18) The position statement asserted that patients should not be deemed ineligible for renal transplantation based on age alone, and that, for select elderly patients, transplantation is superior to dialysis in increasing survival. Before elderly patients should be considered for transplantation, psychological testing and assessments of comorbidities (in particular, cardiac evaluation and malignancy testing) should be performed.

British Transplantation Society
In 2014, the British Transplantation Society published guidelines on the management of the failed kidney transplant.(19) Among the recommendations, the guidelines stated that appropriate patients with failing kidney transplants can
undergo retransplantation when the graft eGFR falls to 10 to 15 mL/min. In addition, the guidelines included a suggestion that joint transplant or advanced kidney care be initiated at least 6 to 12 months before the expected need for dialysis or retransplantation, or when the eGFR is less than 20 mL/min. These recommendations were based on low-quality evidence.

American Society of Transplant Surgeons 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 position statement recommending the modification of the National Organ Transplant Act of 1984.(20) 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 was passed allowing the use of this group of organ donors.

British HIV Association and British Transplantation Society
In 2006, the British HIV Association and British Transplantation Society published guidelines for kidney transplantation in patients with HIV disease.(21) The guidelines recommended that any patient with end-stage renal disease (ESRD) with a life expectancy of at least 5 years should be considered appropriate for transplantation under the following conditions:

a. “CD4 ≥ 200 cells/microlitre for at least six months
b. Undetectable HIV viremia (< 50 copies/ml) for at least 6 months
c. Demonstrable adherence and a stable HAART regimen for ≥ 6 months
d. Absence of AIDS-defining illness following successful immune reconstitution after HAART”

The document listed general and disease-specific exclusion criteria and immunosuppressant protocols. These recommendations were based on level III evidence (observational studies and case reports).

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
The Medicare Benefit Policy Manual includes a chapter on ESRD.(22) 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**

A search of ClinicalTrials.gov in November 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

References:
17. Farrington K, Covic A, Aucella F, et al. Clinical Practice Guideline on management of older patients with chronic kidney disease stage 3b or higher (eGFR <45 mL/min/1.73 m2). Nephrol Dial Transplant. Nov 2016;31(suppl 2):ii1-ii66. PMID 27807144


**Billing Coding/Physician Documentation Information**

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<thead>
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<td>50300</td>
<td>Donor nephrectomy, with preparation and maintenance of allograft, from cadaver donor, unilateral or bilateral</td>
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<tr>
<td>50320</td>
<td>Donor nephrectomy, open from living donor (excluding preparation and maintenance of allograft)</td>
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<td>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</td>
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<td>50325</td>
<td>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</td>
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<td>Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor</td>
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**ICD-10 Codes**

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<tr>
<td>N18.1-</td>
<td>Chronic kidney disease (CKD) code range</td>
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<td>N18.9</td>
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<tr>
<td>N13.8</td>
<td>Obstructive and reflux uropathy unspecified</td>
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<tr>
<td>N13.9</td>
<td>Systemic lupus erythematosus unspecified</td>
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</table>
M32.0- M32.8  Systemic lupus erythematosus
M31.30, M31.31  Wegner’s granulomatosis
N17.1  Acute kidney failure with acute cortical necrosis
D69.0  Allergic purpura
D59.3  Hemolytic-uremic syndrome
N17.0  Acute kidney failure with tubular necrosis
N26.9  Renal sclerosis nos
N28.0  Ischemia and infarction of kidney
N11.9  Chronic tubule-interstitial nephritis unspecified
N05.0- N05.9  Unspecified nephritic syndrome unspecified code range
N03.0- N03.9  Chronic nephritic syndrome code range
T45.8x1- T45.8x6  Poisoning by adverse effect of and underdosing of other primarily systemic and hematologic agents code range
Q61.11- Q61.3  Polycystic kidney disease code range
Q61.5  Medullary cystic kidney
E83.50- E83.59  Disorders of calcium metabolism code range
M10.30- M10.39  Gout due to renal impairment code range
E85.0- E85.9  Amyloidosis code range
E77.0- E77.9  Disorders of glycoprotein metabolism code range
E72.4  Disorders of ornithine metabolism
E74.8  Other specified disorders of carbohydrate metabolism
E74.9  Unspecified disorders of carbohydrate metabolism
Q63.0- Q63.9  Other congenital malformations of the kidney code range
Q61.9  Cystic kidney disease unspecified
Q60.0- Q60.6  Renal agenesis and other defects code range
C90.00- C90.02  Multiple myeloma remission code range
Q85.1  Tuberous sclerosis
S37.00- S37.099  Injury of kidney code range

Additional Policy Key Words
N/A

Policy Implementation/Update Information
8/1/01  New policy.
8/1/02  No policy statement changes.
8/1/03  No policy statement changes.
8/1/04  Policy statement revised to indicate medullary cystic disease as a medically necessary indication. Added HIV+ status as investigational.
8/1/05  Policy statement revised to remove HIV+ status as investigational.
4/1/06  Added general criteria to the Considerations section.
8/1/06  No policy statement changes.
8/1/07  No policy statement changes.
8/1/08  No policy statement changes.
8/1/09  No policy statement changes.
8/1/10  No policy statement changes.
8/1/11  Not medically necessary statement added specifying criteria indicating absolute contraindications to kidney transplantation.
8/1/12  No policy statement changes.
8/1/13  Contraindications combined (absolute and relative) and moved to Considerations section. Statement added that kidney retransplant after a failed primary kidney transplant may be considered medically necessary.
8/1/14  Statement added that kidney transplantation is considered investigational in all other situations, previously said it was not medically necessary.
8/1/15  No policy statement changes.
8/1/16  No policy statement changes.
8/1/17  No policy statement changes.

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