Kidney transplants with either a living or cadaver donor may be considered medically necessary for carefully selected candidates with end-stage renal disease (ESRD). (See Policy Guidelines)

Kidney retransplant after a failed primary kidney transplant may be considered medically necessary in patients who meet criteria for kidney transplantation.

Kidney transplant is considered investigational in all other situations.

Policy Guidelines

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

Human Immunodeficiency Virus (HIV)-positive patients, who meet the following criteria, as stated in the 2001 guidelines of the American Society of Transplantation (Steinman et al, 2001), could be considered candidates for kidney transplantation:
- CD4 count greater than 200 cells/mm³ for more than 6 months
- Undetectable HIV-1 RNA
- On stable antiretroviral therapy for more than 3 months
- No other complications from Acquired Immune Deficiency Syndrome (AIDS) (e.g., opportunistic infection, including aspergillosis, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi sarcoma, other neoplasm)
- 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.

Coding

Etiologies of end-stage renal disease (ESRD) include, but are not limited to, any of the following conditions associated with ESRD (see Table PG1).

Table PG1. ICD-10-CM Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N13.9</td>
<td>Obstructive and reflux uropathy unspecified</td>
</tr>
<tr>
<td>M32.9</td>
<td>Systemic lupus erythematosus unspecified</td>
</tr>
<tr>
<td>M32.0-M32.8</td>
<td>Systemic lupus erythematosus</td>
</tr>
<tr>
<td>M30.0-M30.8</td>
<td>Polyarteritis nodosa and related conditions</td>
</tr>
<tr>
<td>M31.30</td>
<td>Wegner's granulomatosis</td>
</tr>
<tr>
<td>M31.31</td>
<td>Acute kidney failure with acute cortical necrosis</td>
</tr>
<tr>
<td>N17.1</td>
<td>Allergic purpura (includes Henoch-Schönlein purpura)</td>
</tr>
</tbody>
</table>
**7.03.01  Kidney Transplant**

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>D59.3</td>
<td>Hemolytic-uremic syndrome</td>
</tr>
<tr>
<td>N17.0</td>
<td>Acute kidney failure with tubular necrosis</td>
</tr>
<tr>
<td>I12.9</td>
<td>Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease</td>
</tr>
<tr>
<td>N26.9</td>
<td>Renal sclerosis NOS</td>
</tr>
<tr>
<td>N28.0</td>
<td>Ischemia and infarction of kidney (includes renal artery occlusion)</td>
</tr>
<tr>
<td>I82.3</td>
<td>Embolism and thrombosis of renal vein</td>
</tr>
<tr>
<td>N11.9</td>
<td>Chronic tubule-interstitial nephritis unspecified</td>
</tr>
<tr>
<td>N05.0-N05.9</td>
<td>Unspecified nephritic syndrome unspecified code range (includes focal glomerulosclerosis, glomerulonephritis and nephritis)</td>
</tr>
<tr>
<td>N03.0-N03.9</td>
<td>Chronic nephritic syndrome code range</td>
</tr>
<tr>
<td>N02.8</td>
<td>Recurrent and persistent hematuria with other morphologic changes (includes IgA nephropathy)</td>
</tr>
<tr>
<td>M31.0</td>
<td>Hypersensitivity angitis (includes antilglomerular basement membrane [anti-GBM] disease)</td>
</tr>
<tr>
<td>T45.8x1-T45.8x6</td>
<td>Poisoning by adverse effect of and underdosing of other primarily systemic and hematologic agents code range</td>
</tr>
<tr>
<td>Q61.11-Q61.3</td>
<td>Polycystic kidney disease code range</td>
</tr>
<tr>
<td>Q61.5</td>
<td>Medullary cystic kidney</td>
</tr>
<tr>
<td>E83.50-E83.59</td>
<td>Disorders of calcium metabolism code range (includes nephrocalcinosis)</td>
</tr>
<tr>
<td>M10.30-M10.39</td>
<td>Gout due to renal impairment code range</td>
</tr>
<tr>
<td>E85.0-E85.9</td>
<td>Amyloidosis code range</td>
</tr>
<tr>
<td>E75.21</td>
<td>Fabry (-Anderson) disease</td>
</tr>
<tr>
<td>E77.0-E77.9</td>
<td>Disorders of glycoprotein metabolism code range</td>
</tr>
<tr>
<td>E72.4</td>
<td>Disorders of ornithine metabolism</td>
</tr>
<tr>
<td>E74.8</td>
<td>Other specified disorders of carbohydrate metabolism</td>
</tr>
<tr>
<td>E74.9</td>
<td>Unspecified disorders of carbohydrate metabolism</td>
</tr>
<tr>
<td>Q63.0-Q63.9</td>
<td>Other congenital malformations of the kidney code range</td>
</tr>
<tr>
<td>Q61.9</td>
<td>Cystic kidney disease unspecified</td>
</tr>
<tr>
<td>Q60.0-Q60.6</td>
<td>Renal agenesis and other defects code range</td>
</tr>
<tr>
<td>C64.1-C64.9</td>
<td>Malignant neoplasm of kidney, except renal pelvis (includes renal cell carcinoma and Wilms tumor)</td>
</tr>
<tr>
<td>C90.00-C90.02</td>
<td>Multiple myeloma remission code range</td>
</tr>
<tr>
<td>Q85.1</td>
<td>Tuberous sclerosis</td>
</tr>
<tr>
<td>S37.00-S37.099</td>
<td>Injury of kidney code range</td>
</tr>
</tbody>
</table>

**Description**

Kidney transplant, a treatment option for end-stage renal disease (ESRD), involves the surgical removal of a kidney from a cadaver, living-related donor, or living-unrelated donor and transplantation into the recipient.

**Related Policies**

- Allogeneic Pancreas Transplant
- Plasma Exchange

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these
instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**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**

**Background**

End-stage renal disease (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 m². 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.

**Literature Review**

Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

**Kidney Transplant Survival**

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 97.0% (95% confidence interval [CI], 96.8% to 97.1%). Five-year survival was 85.8% (95% CI, 85.5% to 86.1%).²

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.³ Authors found significantly higher 1- and 5-year survival in patients who underwent a kidney transplant than in those who remained on dialysis (authors did not report exact survival rates).

**Organ Donation**

The United Network for Organ Sharing 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.⁴ In 2016, Querard et al conducted a
systematic review and meta-analysis of studies comparing survival outcomes with ECD vs 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. These types of studies have provided mixed findings. For example, Segev et al (2010) found 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 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 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:

- CD4 count greater than 200 cells/mm³ for more than 6 months
- Undetectable HIV-1 RNA
- On stable anti-retroviral therapy for more than 3 months
- No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi sarcoma, or other neoplasm)
- Meeting all other criteria for transplantation.

(Note: the above criteria may be extrapolated to other organs.) 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. 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. 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 2017 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).

In addition, in 2015, Sawinski et al analyzed survival outcomes in patients infected with HIV, HCV, or HIV plus HCV. Analysis included 492 HIV-infected patients, 5605 HCV-infected patients, 147
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. The studies included 133,350 transplant recipients. In an adjusted analysis, the risk of all-cause mortality was significantly higher in HCV-positive vs 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 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 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 than in those uninfected (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.

**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 outcomes after kidney transplant are conflicting.

In a 2015 analysis of kidney transplant data from the U.K., BMI data were available for 13,536 patients. Authors devised several BMI categories (i.e., <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 (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. 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. The sample included 6055 morbidly obese patients (i.e., 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 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 2016 multivariate analysis of the effect of obesity on transplant outcomes by Kwan et al included 191,091 patients from the Scientific Registry of Transplant Recipients database. 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<0.001 for all
outcomes). The risk of adverse outcomes of obesity increased with increasing BMI (e.g., see Table 1), and was independent of the effect of diabetes.

<table>
<thead>
<tr>
<th>Body Mass Index, kg/m²</th>
<th>Hazard Ratio</th>
<th>95% Confidence Interval</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 to 29.9</td>
<td>1.015</td>
<td>0.983 to 1.047</td>
<td>0.416</td>
</tr>
<tr>
<td>30 to 34.9</td>
<td>1.104</td>
<td>1.065 to 1.145</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>35 to 39.9</td>
<td>1.216</td>
<td>1.158 to 1.276</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>40+</td>
<td>1.248</td>
<td>1.156 to 1.348</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Type 2 Diabetes**

Lim et al (2017) evaluated all-cause mortality following kidney transplantation in patients with type 2 diabetes from the Australia and New Zealand Dialysis and Transplant registry. Of 10,714 transplant recipients during the study period, 985 (9%) had type 2 diabetes. The 10-year unadjusted overall survival 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<0.001), 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<0.001), 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 type 2 diabetes 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**

**Overall Survival**

According to data analysis from the OPTN between 2008 and 2015, the 1-year survival rate of patients undergoing a repeat kidney transplant was 97.1% (95% CI, 96.7% to 97.5%). The 5-year patient survival rate after a repeat kidney transplant was 87.6% (95% CI, 86.8% to 88.4%). In 2009, Barocci et al in Italy reported on long-term survival after kidney retransplantation. 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.

**Children**

In 2015, Gupta et al retrospectively analyzed OPTN data, focusing on patients who had an initial kidney transplant as children. 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. 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.

**HIV Infection**

In 2017, Shelton et al evaluated outcomes in HIV-infected patients undergoing kidney retransplantation. 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 (e.g., 5-year survival rates ranging from 87% to 96%). Data on retransplant in HIV-infected individuals is too limited to draw conclusions.

Summary of Evidence
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 (e.g., 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). 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, the evidence is limited and the panel issued a separate narrative on the topic. 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. 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 joint position statement recommending modifications to the National Organ Transplant Act of 1984.22 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 permitting use of this group of organ donors.

**British HIV Association et al**

In 2006, the British HIV Association and British Transplantation Society published guidelines for kidney transplantation in patients with HIV disease.23 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.24 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 June 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**


**Documentation for Clinical Review**

Please provide the following documentation (if/when requested):
- History and physical
- Laboratory report(s)
- Transplant consultation/evaluation report and progress notes

**Post Service**
- Operative report(s)

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**
The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>50300</td>
<td>Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral</td>
</tr>
<tr>
<td>CPT®</td>
<td>50320</td>
<td>Donor nephrectomy (including cold preservation); open, from living donor</td>
</tr>
<tr>
<td>CPT®</td>
<td>50323</td>
<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>
</tr>
<tr>
<td>CPT®</td>
<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>
</tr>
<tr>
<td>CPT®</td>
<td>50327</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>CPT®</td>
<td>50328</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each</td>
</tr>
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<td>CPT®</td>
<td>50329</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each</td>
</tr>
<tr>
<td>CPT®</td>
<td>50340</td>
<td>Recipient nephrectomy (separate procedure)</td>
</tr>
<tr>
<td>CPT®</td>
<td>50360</td>
<td>Renal allotransplantation, implantation of graft; without recipient nephrectomy</td>
</tr>
</tbody>
</table>
### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.
Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Transplant Case Management Department. Please call 1-800-637-2066 ext. 3507708 or visit the Provider Portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.