**Preauthorization is required and must be obtained through Case Management.**

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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

**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 mor-
bidity. Data have demonstrated reasonably high survival rates after kidney retransplant (e.g., five-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.

**Policy**

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

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**

Individual transplant facilities may have their own additional requirements or protocols that must be met in order for the patient to be eligible for a transplant at their facility.

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 dependence affecting the ability to adhere to therapy.**

Human immunodeficiency virus-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 greater than six months**
- **Undetectable HIV-1 RNA**
- **On stable antiretroviral therapy greater than three months**
- **No other complications from acquired immune deficiency syndrome (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.
Etiologies of ESRD include, but are not limited to, any of the following conditions associated with ESRD:

- Obstructive and reflux uropathy
- Systemic lupus erythematosus
- Polyarteritis nodosa
- Acute kidney failure with acute cortical necrosis
- Wegener’s granulomatosis
- Allergic purpura including Henoch-Schönlein purpura
- Hemolytic uremic syndrome
- Acute kidney failure with tubular necrosis
- Hypertensive chronic kidney disease
- Renal sclerosis
- Ischemia and infarction of kidney
- Embolism and thrombosis of the renal vein
- Chronic tubule-interstitial nephritis
- IGA nephropathy
- Nephritic syndrome
- Hypersensitivity angiitis
- Anti-glomerular basement membrane disease
- Focal glomerulosclerosis
- Heavy metal poisoning
- Glomerulonephritis
- Polycystic kidney disease
- Medullary cystic disease
- Nephritis
- Nephrocalcinosis
- Gout nephritis
- Amyloidosis
- Fabry’s disease
- Renal cell carcinoma
- Wilms’ tumor
- Cystic kidney disease
- Renal agenesis
- Multiple myeloma in remission
- Tuberous sclerosis
- Trauma requiring nephrectomy/trauma with injury to kidney

**Medicare Advantage**

If a transplant is needed, we arrange to have the Medicare-approved transplant center review and decide whether the patient is an appropriate candidate for the transplant.

**Background**

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 m².¹ 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.² Of these, 66% of the kidneys came from deceased donors and 34% from living donors.
Regulatory Status

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

Related Protocols

Allogeneic Pancreas Transplant
Plasma Exchange

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

19. 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