The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required and must be obtained through Case Management.** 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.

**Description**

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

**Background**

Based on data from the Organ Procurement and Transplantation Network in 2011, about a third of kidney transplants in the U.S. (5,769 of 16,812) were performed using organs from living donors. (1) As of March 23, 2012, the five-year survival rate for kidney transplants performed between 1997 and 2004 was 66.5% for organs from deceased donors and 79.7% for organs from living donors.

Combined kidney pancreas transplant and management of acute rejection of kidney transplant using either intravenous immunoglobulin (IVIg) or plasmapheresis are discussed in separate Protocols.

**Policy (Formerly Corporate Medical Guideline)**

Kidney transplants with either a living or cadaver donor may be 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 uropathy
- Systemic lupus erythematosus
- Polyarteritis
- Wegener’s granulomatosis
- Cortical necrosis
- Henoch-Schönlein purpura
- Hemolytic uremic syndrome
- Acute tubular necrosis
- Hypertensive nephrosclerosis
- Renal artery or vein occlusion
- Chronic pyelonephritis
- IGA nephropathy
- Anti-glomerular base-membrane disease
- Focal glomerulosclerosis
- Analgesic nephropathy with/without medullary necrosis
- Heavy metal poisoning
- Glomerulonephritis
- Polycystic kidney disease
- Medullary cystic disease
- Nephritis
- Nephrocalcinosis
- Gout nephritis
- Amyloid disease
- Fabry’s disease
- Cystinosis
- Oxalosis
- Diabetes mellitus
- Horseshoe kidney
- Renal aplasia or hypoplasia
- Wilms’ tumor
- Renal-cell carcinoma
- Myeloma in remission
- Tuberous sclerosis
- Trauma requiring nephrectomy/trauma with injury to kidney.

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

Policy Guideline

General

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.

HIV (human immunodeficiency virus)-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 > six months
• HIV-1 RNA undetectable
• On stable anti-retroviral therapy > three months
• No other complications from AIDS (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.

**Benefit Application**

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.

**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.

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.


