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.

**RELATED PROTOCOLS**

Allogeneic Pancreas Transplant
Chelation Therapy for Off-Label Uses

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**DESCRIPTION**

Kidney transplant, a treatment option for end-stage renal disease, 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 end-stage renal disease 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 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 posttransplantation 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.

**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 dependency affecting ability to adhere to therapy.

**RENAL-SPECIFIC CRITERIA**

Indications for renal transplant include a creatinine level of greater than eight mg/dL, or greater than six 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.

**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

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 supports 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 2020, 39,036 transplants were performed in the United States procured from almost 33,500 deceased donors and 5800 living donors.² Kidney transplants were the most common procedure with 22,817 transplants performed from both deceased and living donors in 2020. Since 1988, the cumulative number of kidney transplants is over 502,000.³ Of the cumulative total, 77% of the kidneys came from deceased donors and 23% 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 stage 5 and is defined as a glomerular filtration rate (GFR) less than 15 mL/min/1.73 m².⁴ Patients with advanced chronic kidney disease, mainly stage 4 (GFR 15 to 29 mL/min/1.73 m²) and stage 5 (GFR <15 mL/min/1.73 m²), should be evaluated for transplant.⁵ 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.⁶,⁷

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

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.

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