

(70301)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/15	<b>Next Review Date:</b> 03/21
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 11/14, 11/15, 11/16, 03/17, 03/18, 03/19, 03/20	

**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.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>With end-stage renal disease without contraindications to kidney transplant</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Kidney transplant from a living donor or deceased (cadaveric) donor</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medical management</li> <li>Dialysis</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Morbid events</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With a failed kidney transplant without contraindications to kidney transplant</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Kidney retransplant from a living donor or deceased (cadaveric) donor</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medical management</li> <li>Dialysis</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Morbid events</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>

### 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 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., five-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 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 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

### 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 m<sup>2</sup>.<sup>1</sup>

### Treatment

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; it can also be used as a temporary measure in patients awaiting a 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, in 2017, over 10,300 kidney transplants were performed in the U. S. Since 1988, the cumulative number of kidney transplants is over 435,500.<sup>2</sup> Of the cumulative total, 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 protocols.

## REGULATORY STATUS

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

The U.S. Food and Drug Administration 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. Kidney transplants are included in these regulations.

## RELATED PROTOCOL

Allogeneic Pancreas Transplant

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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.

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