

(70301)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/15	<b>Next Review Date:</b> 03/19
<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	

***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 (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/mm<sup>3</sup> 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 m<sup>2</sup>.<sup>1</sup> 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.<sup>2</sup> 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

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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.

1. National Kidney Foundation. Glomerular Filtration Rate (GFR). 2015; <https://www.kidney.org/atoz/content/gfr>. Accessed August 31, 2017.
2. Organ Procurement and Transplantation Network. View Data Reports. n.d.; <https://optn.transplant.hrsa.gov/data/view-data-reports/>. Accessed August 31, 2017.
3. Krishnan N, Higgins R, Short A, et al. Kidney transplantation significantly improves patient and graft survival irrespective of BMI: a cohort study. *Am J Transplant*. Sep 2015; 15(9):2378-2386. PMID 26147285
4. Querard AH, Foucher Y, Combescure C, et al. Comparison of survival outcomes between Expanded Criteria Donor and Standard Criteria Donor kidney transplant recipients: a systematic review and meta-analysis. *Transpl Int*. Apr 2016; 29(4):403-415. PMID 26756928
5. Segev DL, Muzaale AD, Caffo BS, et al. Perioperative mortality and long-term survival following live kidney donation. *Jama*. Mar 10 2010; 303(10):959-966. PMID 20215610
6. Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation*. May 15, 2001; 71(9):1189-1204. PMID 11397947
7. Locke JE, Reed RD, Mehta SG, et al. Center-level experience and kidney transplant outcomes in HIV-infected recipients. *Am J Transplant*. Aug 2015; 15(8):2096-2104. PMID 25773499
8. Locke JE, Mehta S, Reed RD, et al. A national study of outcomes among HIV-infected kidney transplant recipients. *J Am Soc Nephrol*. Sep 2015; 26(9):2222-2229. PMID 25791727
9. Locke JE, Gustafson S, Mehta S, et al. Survival benefit of kidney transplantation in HIV-positive kidney transplant patients compared with HCV-infected or HIV/HCV-coinfected recipients. *Kidney Int*. Aug 2015; 88(2):341-349. PMID 25807035
10. Sawinski D, Forde KA, Eddinger K, et al. Superior outcomes in HIV-positive kidney transplant patients compared with HCV-infected or HIV/HCV-coinfected recipients. *Kidney Int*. Aug 2015; 88(2):341-349. PMID 25807035

11. Fabrizi F, Martin P, Dixit V, et al. Meta-analysis of observational studies: hepatitis C and survival after renal transplant. *J Viral Hepat.* May 2014; 21(5):314-324. PMID 24716634
12. Gill JS, Lan J, Dong J, et al. The survival benefit of kidney transplantation in obese patients. *Am J Transplant.* Aug 2013; 13(8):2083-2090. PMID 23890325
13. Pieloch D, Dombrowskiy V, Osband AJ, et al. Morbid obesity is not an independent predictor of graft failure or patient mortality after kidney transplantation. *J Ren Nutr.* Jan 2014; 24(1):50-57. PMID 24070588
14. Kwan JM, Hajjiri Z, Metwally A, et al. Effect of the obesity epidemic on kidney transplantation: obesity is independent of diabetes as a risk factor for adverse renal transplant outcomes. *PLoS One.* 2016; 11(11):e0165712. PMID 27851743
15. Lim WH, Wong G, Pilmore HL, et al. Long-term outcomes of kidney transplantation in people with type 2 diabetes: a population cohort study. *Lancet Diabetes Endocrinol.* Jan 2017; 5(1):26-33. PMID 28010785
16. Barocci S, Valente U, Fontana I, et al. Long-term outcome on kidney retransplantation: a review of 100 cases from a single center. *Transplant Proc.* May 2009; 41(4):1156-1158. PMID 19460504
17. Gupta M, Wood A, Mitra N, et al. Repeat kidney transplantation after failed first transplant in childhood: past performance informs future performance. *Transplantation.* Aug 2015; 99(8):1700-1708. PMID 25803500
18. Shelton BA, Mehta S, Sawinski D, et al. Increased mortality and graft loss with kidney retransplantation among human immunodeficiency virus (HIV)-infected recipients. *Am J Transplant.* Jan 2017; 17(1):173-179. PMID 27305590
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 m<sup>2</sup>). *Nephrol Dial Transplant.* Nov 2016; 31(suppl 2):ii1-ii66. PMID 27807144
20. Segall L, Nistor I, Pascual J, et al. Criteria for and appropriateness of renal transplantation in elderly patients with end-stage renal disease: a literature review and position statement on behalf of the European Renal Association-European Dialysis and Transplant Association Descartes Working Group and European Renal Best Practice. *Transplantation.* Oct 2016; 100(10):e55-65. PMID 27472096
21. Andrews PA, Standards Committee of the British Transplantation Society. Summary of the British Transplantation Society Guidelines for management of the failing kidney transplant. *Transplantation.* Dec 15 2014; 98(11):1130-1133. PMID 25299519
22. American Society of Transplant Surgeons (ASTS), The American Society of Transplantation (AST), The Association of Organ Procurement Organizations (AOPO), et al. Statement on transplantation of organs from HIV-infected deceased donors. 2011; <http://asts.org/docs/default-source/position-statements/transplantation-of-organs-from-hiv-infected-deceased-donors-july-22-2011.pdf?sfvrsn=4>. Accessed August 31, 2017.
23. Bhagani S, Sweny P, Brook G, et al. Guidelines for kidney transplantation in patients with HIV disease. *HIV Med.* Apr 2006; 7(3):133-139. PMID 16494626
24. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual: Chapter 11 - End Stage Renal Disease (ESRD). 2016; <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf>. Accessed August 31, 2017.