

Corporate Medical Policy

Renal (Kidney) Transplantation

File Name: renal_kidney_transplantation
Origination: 4/1980
Last CAP Review: 8/2018
Next CAP Review: 4/2019
Last Review: 8/2018

Description of Procedure or Service

A kidney transplant, a treatment for end-stage renal disease (ESRD), involves the surgical removal of a kidney from a cadaver, living-related, or living unrelated donor and transplantation into the recipient.

End-stage renal disease (ESRD) refers to the inability of kidney functions to be performed, such as filtering wastes and excess fluids from the blood. ESRD, also known as stage 5 chronic renal failure is life-threatening, and is defined as a glomerular filtration rate (GFR) less than 15mL/min/1.73m². 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 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, in 2017, over 10,300 kidney transplants were performed in the United States. Since 1988, the cumulative number of kidney transplants is over 435,500. Of the cumulative total, 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 Food and Drug Administration (FDA).

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. Kidney transplants are included in these regulations.

Related Policies:

Hemodialysis Treatment for ESRD

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Renal (Kidney) Transplantation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Renal (Kidney) Transplantation is covered

Kidney transplants with either a living or cadaveric donor may be considered medically necessary for carefully selected candidates with end-stage renal disease as indicated below:

1. The patient must meet the eligibility criteria for the transplant center performing the procedure.
2. The patient must be willing and capable of following the post transplant treatment plan.

Kidney re-transplant after a failed primary kidney transplant may be considered medically necessary in patients who meet criteria for kidney transplant.

When Renal (Kidney) Transplantation is not covered

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

Coverage is not provided if the procedure is expected to be futile due to co-morbid disease or if post-transplantation care is expected to significantly worsen co-morbid conditions.

Coverage is not provided for organs sold rather than donated to a recipient.

Coverage is not provided for artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

Policy Guidelines

Only those patients accepted for transplantation by a transplantation center and actively listed for transplant should be considered for precertification or prior approval. Guidelines should be followed for transplant network or consortiums, if applicable.

Consideration for listing for renal transplant may start well before end-stage levels of renal function are reached, based upon the anticipated time that a patient may spend on the waiting list, or availability of living donors.

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Kidney transplantation is not recommended in patients in whom the procedure is expected to be futile due to co-morbid disease or in whom post-transplantation care is expected to significantly worsen co-morbid conditions.

Patients infected with HIV may receive organs from HIV-positive donors under approved research protocols through the HIV Organ Policy Equity Act. As of November 2017, six hospitals performed 34 such transplants (23 kidney and 11 liver transplants), involving organs from 14 deceased donors. In a prospective, nonrandomized study, Muller and colleagues (2015) noted that HIV-positive patients transplanted with kidneys from donors testing positive for HIV showed a 5-year survival rate of 74%. Researchers noted that the HIV infection remained well-controlled and the virus was undetectable in the blood after transplantation.

Currently, Organ Procurement and Transplantation Network (OPTN) policy permits HIV-positive transplant candidates.

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney transplantation in patients with HIV disease. These criteria may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy
- Cluster of differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- No opportunistic infections for at least 6 months
- • No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 50300, 50320, 50323, 50325, 50327, 50328, 50329, 50340, 50360, 50365, 50370, 50380, 50547, S2152.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 12/95

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Review - 12/01

BCBSA Medical Policy Reference Manual, 7.03.01; 7/12/02

Specialty Matched Consultant review - 11/03

BCBSA Medical Policy Reference Manual, 7.03.01; 2/25/04

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BCBSA Medical Policy Reference Manual, 7.03.01; 3/15/05

BCBSA Medical Policy Reference Manual, 7.03.01; 4/1/05

Steinman TI, Becker BN, Frost AE et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation* 2001; 71(9):1189-204.

Stock PG, Barin B, Murphy B et al. Outcomes of kidney transplantation in HIV-infected recipients. *N Engl J Med* 2010; 363(21):2004-14. Retrieved on May 24, 2012 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3028983/?tool=pubmed>

Trullas JC, Cofan F, Tuset M et al. Renal transplantation in HIV-infected patients: 2010 update. *Kidney Int* 2011; 79(8):825-42. Retrieved on May 24, 2012 from <http://www.medscape.com/viewarticle/741413>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 5/10/12

U.S. Department of Health and Human Services Organ Procurement and Transplantation Network.

Retrieved on July 21, 2014 from <http://optn.transplant.hrsa.gov/latestData/step2.asp>.

Medical Director review 7/2012

National Kidney Foundation (KDOQI) Clinical Practice Guidelines For Chronic Kidney Disease: Evaluation, Classification and Stratification. 2002.

http://www.kidney.org/professionals/kdoqi/pdf/ckd_evaluation_classification_stratification.pdf

Medical Director review 3/2013

Specialty Matched Consultant Advisory Panel review 4/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 5/9/13

Medical Director review 6/2013

Medical Director review 4/2014

Specialty Matched Consultant Advisory Panel review 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 6/12/14

Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 6/11/15

Specialty Matched Consultant Advisory Panel review 4/2016

Medical Director review 4/2016

National Kidney Foundation. Glomerular Filtration Rate (GFR). <https://www.kidney.org/atoz/content/gfr>; retrieved on December 2016.

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U.S. Department of Health and Human Services Organ Procurement and Transplantation Network. Data reports. <https://optn.transplant.hrsa.gov/data/viewdata-reports/>; retrieved December 2016.

Medical Director review 12/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 6/2016

Specialty Matched Consultant Advisory Panel review 4/2017

Medical Director review 4/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 9/2017

Specialty Matched Consultant Advisory Panel review 4/2018

Medical Director review 4/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.01, 8/2018

Medical Director review 8/2018

Policy Implementation/Update Information

4/80 Original Policy: Generally accepted medical practice

6/83 Reaffirmed

8/88 Reviewed: Eligible for coverage

11/90 Revised: Coverage language

Local Review Dates:

1/93 Reviewed: PCP Physician Advisory Group

11/94 Reviewed: PCP Physician Advisory Group

11/95 Reviewed: PCP Physician Advisory Group

6/96 Reviewed: Listed medically necessary conditions for coverage

8/97 Reaffirmed

9/99 Reformatted, Description of Procedure or service changed, Medical Term Definitions added.

12/99 Medical Policy Advisory Group

3/01 System change.

12/01 Specialty Matched Consultant Review. Policy revised per consultant's recommendations. Format changes.

12/03 Specialty Matched Consultant review 11/18/03. No changes to criteria. Description revised for clarity. Benefits Application and Billing/Coding sections revised.

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- 4/04 Code S2152 added in Billing/Coding section of policy.
- 1/6/05 Codes 50323, 50325, 50327, 50328, 50329 added to Billing/Coding section of policy.
- 11/3/05 Removed HIV positivity from "When not Covered" section. Criteria added under "When Covered" section for asymptomatic HIV positive patients. Additional information added to "Policy Guidelines" section regarding Kidney transplant in HIV positive patients. Policy status changed to "Active policy, no longer scheduled for routine literature review."
- 6/22/10 Policy Number(s) removed (amw)
- 7/24/12 Policy returned to active status and will undergo routine literature review. Description section updated. "When Covered" section reformatted and list of etiologies associated with end stage renal disease deleted. "When not Covered" section updated as follows: "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." Deleted list of participating transplant facilities from Policy Guidelines. Policy Guidelines updated. References updated. Medical Director review 7/2012. (mco)
- 5/14/13 Specialty Matched Consultant Advisory Panel review 4/2013. Medical Director review 3/2013. References updated. Added the following statement to the "When not Covered" section: "Coverage is not provided if the procedure is expected to be futile due to co-morbid disease or if post-transplantation care is expected to significantly worsen co-morbid conditions." (mco)
- 7/1/13 Added the following statement to "When Covered" section: "Kidney re-transplant after a failed primary kidney transplant may be considered medically necessary." References updated. Medical Director review 6/2013. (mco)
- 5/13/14 Medical Director review 4/2014. Specialty Matched Consultant Advisory Panel review 4/2014. No changes to Policy Statements. (mco)
- 8/12/14 "When Covered" item #4 revised from "Kidney re-transplant after a failed primary kidney transplant may be considered medically necessary." to "Kidney re-transplant after a failed primary kidney transplant may be considered medically necessary in patients who meet criteria for kidney transplant." Description section updated. References updated. (mco)
- 5/26/15 References updated. Specialty Matched Consultant Advisory Panel review 4/2015. Medical Director review 4/2015. (td)
- 7/28/15 Description updated: added Regulatory Status information. References updated. Policy Statements unchanged. (td)
- 5/31/16 Specialty Matched Consultant Advisory Panel review 4/27/2016. Medical Director review 4/2016. (jd)

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- 1/27/17 Description section updated. Added Related Policy for policy titled: “Hemodialysis Treatment for ESRD”. References updated. Medical Director review 12/2016. (jd)
- 5/26/17 Specialty Matched Consultant Advisory Panel review 4/2017. Medical Director review 4/2017. (jd)
- 5/11/18 Moved HIV criteria from the When covered section to the Policy Guidelines and reformatted the When Covered section. No change to policy intent. References updated. Specialty Matched Consultant Advisory Panel review 4/2018. Medical Director review 4/2018. (jd)
- 9/28/18 Description section, regulatory status, policy guidelines and references updated. No change to policy intent. Medical Director review 8/2018. (jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.