TITLE: KIDNEY TRANSPLANTATION

EFFECTIVE DATE: April 22, 2019

This policy was developed with input from specialists in endocrinology, nephrology and transplant surgery, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY
These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of kidney transplantation. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND
I. Definitions
   A. ABO incompatible kidney transplant is a procedure which allows kidneys to be transplanted across blood type barriers.
   B. Deceased donor kidney transplant is a procedure in which a kidney of a deceased individual is removed and transplanted into a different individual. There are currently three different categories of deceased donors: deceased brain death (DBD) donors, deceased cardiac death (DCD) donors, and expanded criteria donors (ECD). The decision for the use of these organs is left to the transplant institution and the organ recipient.
   C. Expanded criteria donor kidneys are those that are over 85% on the Kidney Donor Profile Index (KDPI), which takes into account ten criteria from the Kidney Donor Risk Index (KDRI) that include age, height, weight, ethnicity, history of hypertension, history of diabetes, cause of death, serum creatinine, hepatitis C virus status, and donation after circulatory death (DCD) status.
   D. Living donor kidney transplant is a procedure in which a kidney of a healthy individual is removed and transplanted into a related (or unrelated) recipient.
   E. A paired donor exchange, also known as donor swap, allows individuals who have willing but incompatible donors to “exchange” kidneys with other donors, making two compatible living donor transplants possible.
   F. Positive crossmatch is a situation in which the potential recipient has antibodies against the donor’s antigens, making them incompatible. Positive crossmatch kidney transplant is similar to the process used for ABO-incompatible living-donor kidney transplants, in which individuals receive kidneys from living donors with blood types incompatible with their own. Positive crossmatch live donor kidney transplants are usually only performed if no other live donors (with a negative crossmatch) exist.
   G. Substance use disorder, as defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is a problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress. The symptoms associated with a substance use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).
H. **Transplant or graft** is a portion of the body or a complete organ removed from its natural site and transferred to a separate site in the same or different individual. Kidney transplantation is performed to correct uremia in individuals with end-stage renal disease by restoring kidney function with an adequately functioning kidney. It is used as an alternative to kidney dialysis.

I. Transplant **evaluation** is a physical and psychosocial exam to determine if an individual is an acceptable candidate for transplantation. The specific exams and tests depend on the individual’s diagnosis and health history and vary from hospital to hospital. Tests may include the following: cardiac evaluation; lung function tests; lab tests, including blood typing, chemistry panels, and serology testing for hepatitis, HIV and other common viruses; appropriate cancer surveillance, as indicated (e.g., colonoscopy, pap smear, mammogram, prostate cancer screening); dental evaluation with treatment of existing problems; psychosocial evaluation. Additional testing or clearance may be required to address other significant coexisting medical conditions.

II. **Comments**
Bilateral nephrectomy may be indicated when the individual’s own diseased kidneys are the cause of severe uncontrolled hypertension or when they are the source of persistent urinary tract infections. This procedure may also be indicated in some cases of polycystic kidney disease when the size of the kidneys cause symptoms or when the kidneys occupy the area of the pelvis needed for the renal transplant, although unilateral nephrectomy may be sufficient.

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**BENEFIT CONSIDERATIONS**

1. Prior authorization **is required** for:
   - Kidney Transplant **Evaluation**
   - Kidney **Transplantation**
   - Please see the prior authorization list for product specific prior authorization requirements.

2. Coverage may vary according to the terms of the member’s plan document.

3. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member’s plan document.

4. Request for incompatible ABO, positive crossmatch, or other crossmatch abnormalities require medical director review.

5. Complex cases require medical director or external review and, as necessary, discussion with the individual’s physician.

6. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.

7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

8. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica Provider Administrative Manual.

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**MEDICAL NECESSITY CRITERIA**

I. Indications for Kidney Transplant **Evaluation** [NOTE: For multiorgan transplant, the individual must meet criteria for each organ. Please refer to applicable Medica UM policy.]
   
   Documentation in the medical records indicates that the individual has one of the following diagnoses:
   
   A. End-Stage Renal Disease (ESRD) as defined by **one of the following**:
      1. Chronic kidney disease (CKD) with a glomerular filtration rate (GFR) less than or equal to 20 ml/min/m²
      2. CKD on dialysis
   
   B. Anticipated ESRD as defined above within the next 12 months.

II. Indications for Kidney **Transplantation**
   
   Documentation in the medical records indicates that all of the following criteria are met:
   
   A. Individual meets the institution’s recipient suitability criteria for transplant
   
   B. The individual meets all of the criteria in section I above
   
   C. Individual or guardian is able to give informed consent. Individual/guardian and family/social support system are able to comply with the treatment regimen and the necessary follow-up. Inadequate funding to pay for immunosuppressive medications post-transplant is addressed and resolved
   
   D. For individuals with a recent (24 months) history of substance use disorder, successful completion of a chemical dependency program and 6 months of documented ongoing abstinence
E. None of the following contraindications are present:
   1. Uncorrectable non-renal medical condition that would itself significantly shorten life expectancy or make transplant success unlikely
   2. Reversible renal failure
   3. Active systemic or localized infection
   4. Irreversible multisystem organ failure
   5. Active untreated or untreatable malignancy (NOTE: Individuals with underlying malignancy may require oncology consult to assess prognosis and risk of recurrence)
   6. HIV infection with detectable viral load and CD4 counts less than 200/mm³, acquired immunodeficiency syndrome (AIDS) or AIDS-defining condition (See Appendix 1)
   7. Active substance use disorder
   8. Irreversible severe brain damage
   9. Limited irreversible rehabilitative potential
   10. Post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI
   11. Ongoing pattern of noncompliance, psychiatric illness, psychological condition, or limited cognitive ability that would make compliance with a disciplined medical regimen impossible
   12. Lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver
   13. Inability to obtain informed consent from individual or guardian.

III. Indications for Kidney Retransplantation
   Documentation in the medical records indicates that all of the following criteria are met:
   A. Failed kidney transplant
   B. The above criteria in section II for initial transplantation must be met
   C. Documentation of compliance with post-transplant treatment regimen during the 18 months preceding the request.

06/2016 MPC

02/2017 MPC
27. Centers for Medicare & Medicaid Services (CMS). End Stage Renal Disease (ESRD). In: *Medicare Benefit Policy Manual (#100.2).* Rev. 224, 06-03-16. CMS; Baltimore, MD.

02/2018 MPC
APPENDIX 1 – AIDS-Defining Conditions

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive†
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month’s duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age greater than 1 month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy attributed to HIV§
- Herpes simplex: chronic ulcers (greater than 1 month’s duration) or bronchitis, pneumonitis, or esophagitis (onset at age greater than 1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (greater than 1 month’s duration)
- Kaposi sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis jirovecii (previously known as “Pneumocystis carinii”) pneumonia
- Pneumonia, recurrent†
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain, onset at age greater than 1 month
- Wasting syndrome attributed to HIV§

* Only among children aged less than 6 years.
† Only among adults, adolescents, and children aged greater than or equal to 6 years.
§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references:

- CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).
- CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).