Medical Necessity Guidelines: Solid Organ Transplant: Kidney

Effective: July 20, 2017

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Applies to:

- ☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409
- ☒ Tufts Health Public Plans products
  - ☒ Tufts Health Direct — Health Connector; Fax: 888.415.9055
  - ☒ Tufts Health Together — A MassHealth Plan; Fax: 888.415.9055
  - ☒ Tufts Health Unify — OneCare Plan; Fax: 781.393.2607
  - ☒ Tufts Health RITogether — A Rhode Island Medicaid Plan; Fax: 857.304.6404
- ☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW
Renal (kidney) transplantation involves removing a kidney from a donor (either a live donor or a cadaver donor) and implanting it into the patient with kidney failure.

To initiate the prior authorization process, it is necessary to complete and submit the Kidney Transplant Request for Coverage Form to the following address:

Medical Management Intake Services, Tufts Health Plan, 705 Mount Auburn Street, Watertown, MA 02471. Fax: 888.415.9055.

COVERAGE GUIDELINES
Tufts Health Plan may authorize coverage of a kidney transplant for adult and pediatric Members with End Stage Renal Disease (ESRD), of any cause, with a Glomerular Filtration Rate (GFR) < 20 ml/min and/or requiring dialysis, and a satisfactory psychosocial profile, and support systems.

LIMITATIONS
Tufts Health Plan will not authorize the coverage of a kidney transplant in the following circumstances:

- Recurrent infection, uncontrolled or untreated
- Active malignancy
- History of malignancy within past two years, except within the past five years for breast cancer, malignant melanoma and colorectal cancer (no waiting period for treated basal cell cancer of the skin, in situ bladder cancer, and all non-invasive papillary bladder tumors)
- Active Hepatitis B infection
- Nonfunctioning or abnormal lower urinary tract that has not been evaluated and treated by urologist
- Advanced ilio-femoral vascular disease
- Advanced liver disease due to viral or other etiologies
- Untreated active coronary artery disease
- Cardiac ejection fraction < 30 %
- Active pulmonary disease including:
  - home oxygen therapy
  - uncontrolled asthma
  - severe Cor Pulmonale
  - severe COPD/Pulmonary Fibrosis/Restrictive lung disease defined as:
    a. Best FEV₁ < 25% predicted value
    b. RA pO₂ < 60 mmHg
    c. Exercise desaturation to SaO₂ < 90%
    d. Greater than 4 episodes of pneumonia in the past 12 months
- Active drug, substance, or alcohol abuse within the last 6 months
• Active tobacco use within the last 6 months such as actively smoking cigarettes, or using any nicotine delivery system products (e.g., gum, patches, electronic cigarettes)
• Untreated cerebrovascular disease
• Dementia
• Sickle cell anemia with more than three Sickle Cell Crises requiring hospitalization within the previous 24 months.
• Any unresolved psychosocial concerns or a history of noncompliance with medical management including, but not limited to not attending follow-up appointments, not taking prescription medications, and attending dialysis.
• Human immunodeficiency virus (HIV) disease unless ALL of the following are met:
  - Pre-transplant evaluation by an infectious disease specialist with expertise in HIV and transplantation and confirmation of plans for continued follow-up after transplantation with an infectious disease specialist with that expertise.
  - CD4 count greater than 200 cells/mm3
  - Undetectable HIV-1 ribonucleic acid (RNA)
  - Stable anti-retroviral therapy for > than three months
  - Absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections; Kaposi’s sarcoma; or other neoplasm)

### CODES

The following HCPCS/CPT code(s) require prior authorization:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>50300</td>
<td>Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral</td>
</tr>
<tr>
<td>50320</td>
<td>Donor nephrectomy (including cold preservation); open, from living donor</td>
</tr>
<tr>
<td>50323</td>
<td>Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal or perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary</td>
</tr>
<tr>
<td>50325</td>
<td>Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal or perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary</td>
</tr>
<tr>
<td>50327</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>50328</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each</td>
</tr>
<tr>
<td>50329</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each</td>
</tr>
<tr>
<td>50340</td>
<td>Recipient nephrectomy (separate procedure)</td>
</tr>
<tr>
<td>50360</td>
<td>Renal allotransplantation, implantation of graft; without recipient nephrectomy</td>
</tr>
<tr>
<td>50365</td>
<td>Renal allotransplantation, implantation of graft; with recipient nephrectomy</td>
</tr>
<tr>
<td>50370</td>
<td>Removal of transplanted renal allograft</td>
</tr>
<tr>
<td>50380</td>
<td>Renal autotransplantation, reimplantation of kidney</td>
</tr>
<tr>
<td>50547</td>
<td>Laparoscopic donor nephrectomy (including cold preservation), from living donor</td>
</tr>
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### REFERENCES


APPROVAL HISTORY
January 2004: Reviewed by the Medical Affairs Medical Policy Committee

Subsequent endorsement date(s) and changes made:
- April 14, 2007: Criteria placed in new format
- April 25, 2008: Reviewed and renewed without changes
- May 4, 2009: Limitations regarding Members with HIV and noncompliance issues clarified. Limitation for Members with Hepatitis C infection removed. Limitations for Members with Dementia and Sickle Cell Anemia Crises were added.
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- June 2010: BMI limitation removed.
- November 2010: Reviewed by MCMC, no changes.
- October 12, 2011: Reviewed at MSPAC and approved by Integrated Medical Policy Advisory Committee, IMPAC no changes
- December 12, 2012: Reviewed by IMPAC. Advanced ilio-femoral vascular disease and advanced liver disease due to viral or other etiologies added to Limitations.
- August 6, 2013: Tobacco use clarified
- December 11, 2013: Reviewed by IMPAC, renewed without changes.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- July 20, 2016: Reviewed by IMPAC renewed without changes
- December 13, 2016: Contact information updated
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- July 20, 2017: Reviewed by IMPAC, renewed without changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member’s benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on
the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates or other requirements will take precedence. For CareLink℠ Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of these guidelines is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.