Medical Necessity Guidelines: Solid Organ Transplant: Kidney

Effective: October 10, 2018

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

<table>
<thead>
<tr>
<th>Applies to:</th>
<th>Yes ☒</th>
<th>No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMMERCIAL Products</td>
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<tr>
<td>☒Tufts Health Plan Commercial products; Fax: 617.972.9409</td>
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<tr>
<td>☒Tufts Health Freedom Plan products; Fax: 617.972.9409</td>
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<tr>
<td>• CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</td>
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<tr>
<td>TUFTS HEALTH PUBLIC PLANS Products</td>
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<tr>
<td>☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055</td>
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<tr>
<td>☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</td>
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<tr>
<td>☒Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</td>
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<tr>
<td>☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 781.393.2607</td>
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<td>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</td>
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<td>SENIOR Products</td>
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<tr>
<td>• Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List</td>
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<tr>
<td>• Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</td>
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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.

CLINICAL COVERAGE CRITERIA
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 FEVı < 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 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>
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<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>
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<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>
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<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>
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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, no 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
- September 18, 2017: Administrative update
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated

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 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.

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.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline 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.