

Medical Necessity Guidelines: Solid Organ Transplant: Kidney

Effective: October 21, 2020

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p>Applies to:</p> <p>COMMERCIAL Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>TUFTS HEALTH PUBLIC PLANS Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists. <p>SENIOR Products</p> <ul style="list-style-type: none"> • Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List • Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List 	

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 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.
- 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:

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

REFERENCES

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3. Boudville N, Prasad GV, Knoll G, Muirhead n, Thiesson-Philbrook H, Yang RC, et al. Metaanalysis: risk for hypertension in living kidney donors. Ann Intern Med. 2006 Aug 1;145(3):185-96.
4. Danovitch, G. ed. Handbook of Kidney Transplantation. 3rd edition. Philadelphia, PA. Lippincott, Williams and Williams. 2001.
5. Ramos, E, Brennan, D. Evaluation of the potential renal transplant recipient. UpToDate®. December 2006.
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8. Wolfe, R., Ashby, V., Milford, E. et al. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric kidney transplant. New England Journal of Medicine. 1999 Dec 2;341(23): 1725-1730.

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.
- October 15, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- February 23, 2015: Administrative update.
- 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
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- February 19, 2020: Reviewed by IMPAC, removed Limitation language regarding use of nicotine delivery system products (e.g., gum, patches, electronic cigarettes), effective February 19, 2020.
- February 20, 2020: Unify fax number updated
- October 21, 2020: 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 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.

[Provider Services](#)