

Effective: September 1, 2023

<p><b>Prior Authorization Required</b> If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request to the FAX numbers below.</p>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p><b>Notification Required</b> IF <u>REQUIRED</u>, concurrent review may apply</p>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

**Applies to:**

**Commercial Products**

- Harvard Pilgrim Health Care Commercial products; 800-232-0816
- Tufts Health Plan Commercial products; 617-972-9409  
CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
- Tufts Health Unify\* – OneCare Plan (a dual-eligible product); 857-304-6304  
\*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

**Senior Products**

- Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
- Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
- Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

**Note:** While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

**Overview**

Renal (kidney) transplantation is a treatment approach in end-stage renal failure. The surgery replaces a diseased kidney with a healthy kidney from a donor (either a live donor or a cadaver donor).

**To initiate the prior authorization process**, it is necessary to complete and submit the [Kidney Transplant Request for Coverage Form](#).

**Clinical Guideline Coverage Criteria**

The 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.

**Note:** The Plan supports the use of non-race-based calculations of GFR, such as the CKD-EPI Creatinine Equation.

**Limitations**

The Plan will not authorize the coverage of a kidney transplant in Members with **ANY** of the following:

1. Active or uncontrolled alcohol use disorder or substance use disorder
2. Active Hepatitis B infection
3. Active malignancy
4. Active pulmonary disease including:
  - a. home oxygen therapy
  - b. uncontrolled asthma
  - c. severe Cor Pulmonale
  - d. severe COPD /Pulmonary Fibrosis/Restrictive lung disease defined as:
  - e. Best FEV<sub>1</sub> < 25% predicted value
  - f. Ambient pO<sub>2</sub> < 60 mmHg
  - g. Exercise desaturation to SaO<sub>2</sub> < 90%
  - h. Greater than 4 episodes of pneumonia in the past 12 months
5. 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.
6. Advanced ilio-femoral vascular disease
7. Advanced liver disease due to viral or other etiologies
8. Cardiac ejection fraction < 30%
9. Dementia
10. 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)
11. Human immunodeficiency virus (HIV) disease unless **ALL** of the following are met:
12. 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.
13. CD4 count >200 cells/μL during 3 months prior to transplantation
14. Undetectable HIV-1 ribonucleic acid (RNA)
15. Stable anti-retroviral therapy for > 3 months
16. 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)
17. Nonfunctioning or abnormal lower urinary tract that has not been evaluated and treated by urologist
18. Sickle cell anemia with more than three Sickle Cell Crises requiring hospitalization within the previous 24 months
19. Recurrent infection, uncontrolled or untreated
20. Untreated active coronary artery disease
21. Untreated cerebrovascular disease

**Note:** Smoking has been strongly correlated to adverse health and surgical outcomes. There is evidence to show that smoking, both by donors and by recipients, has a major impact on outcomes after organ transplantation. Smoking cessation is strongly recommended for both donors and recipients prior to transplantation

## Codes

The following code(s) require prior authorization:

**Table 1: CPT/HCPCS Codes**

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

Code	Description
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:

1. Blumberg EA, Rogers CC; American Society of Transplantation Infectious Diseases Community of Practice. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. 2019;33(9):e13499. doi:10.1111/ctr.13499.
2. Chadban SJ, Ahn C, Axelrod DA, et al. KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. *Transplantation*. 2020;104(4S1 Suppl 1):S11-S103.
3. Delgado C, Baweja M, Crews DC, et al. A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease [published online ahead of print, 2021 Sep 22]. *Am J Kidney Dis*. 2021;S0272-6386(21)00828-3.
4. Kidney transplantation in adults: Evaluation of the potential kidney transplant recipient: UpToDate.com/login [via subscription only]. Published February 19, 2020. Updated July 2021. Accessed August 18, 2021.
5. Knoll G, Cockfield S, Blydt-Hansen T, et al. Canadian Society of Transplantation: consensus guidelines on eligibility for kidney transplantation. *CMAJ*. 2005;173(10):S1-S25. doi:10.1503/cmaj.1041588.

## Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- November 17, 2021: Reviewed by IMPAC for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan; under the “Limitations” section changed “CD4 count >200 cells/μL” to “CD4 count >200 cells/μL during 3 months prior to transplantation”. Added note to the GFR calculation, “The plan supports the use of non-race-based calculations of GFR, such as the CKD-EPI Creatinine Equation”
- December 1, 2022: Reviewed by MPAC, renewed without changes
- March 15, 2023: Reviewed by MPAC, limitations updated to remove smoking cessation and limitation modified from “Active drug, substance abuse, or alcohol abuse within the last 6 months” to “Active or uncontrolled alcohol use disorder or substance use disorder”. Effective September 1, 2023

## 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. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members

under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.