

Subject: Kidney Transplantation

Guideline #: CG-UM-005

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Description

This document addresses kidney transplantation, involving the removal of the kidney from a *deceased or living donor* with the implantation into a single recipient.

Clinical Indications

Note: *Members must meet the clinical indications as well as the general individual selection criteria for the transplantation to be considered medically necessary.*

Medically Necessary:

Kidney transplantation from a deceased or a living donor is considered **medically necessary** for selected individuals with **end stage renal disease***. The clinical indications leading to end stage renal disease include, but are not limited to, **one** of the conditions listed below.

***Note:** See **Definition section** for further information on **end stage renal disease**.

Clinical Indications:

- Congenital Disorders
 - Aplasia
 - Hypoplasia
 - Horseshoe Kidney

- Toxic Nephropathies
 - Lead nephropathy
 - Analgesic nephropathy
 - Metabolic Disorders
 - Hyperoxaluria
 - Nephrocalcinosis
 - Gout
 - Amyloidosis
 - Cystinosis

- Hereditary Nephropathies
 - Alport's syndrome
 - Polycystic kidney disease
 - Medullary cystic disease
- Irreversible Acute Renal Failure
 - Cortical necrosis
 - Hemolytic uremic syndrome
 - Acute and subacute glomerulonephritis
 - Anaphylactoid purpura (Henoch-Schonlein)
- Irreversible Chronic Renal Failure
 - Chronic pyelonephritis
 - Diabetic nephropathy
 - Chronic glomerulonephritis
 - Hypertensive nephrosclerosis
 - Goodpasture's disease
 - Hypocomplementemic nephritis
 - Steroid-resistant nephrotic syndrome
 - Toxic nephropathy (including nephropathy related to cyclosporine/tacrolimus toxicity)
 - Chronic allograft nephropathy (that is, chronic rejection)
- Tumors Requiring Nephrectomy
 - Renal carcinoma
 - Wilms' tumor
 - Tuberous sclerosis
- Renal Vascular Diseases
 - Renal artery occlusion
 - Renal vein thrombosis
- Obstructive Uropathy
 - Acquired
 - Congenital
- Trauma requiring nephrectomy
- Other Indications
 - Scleroderma
 - Polyarteritis (periarteritis nodosa)
 - Multiple Myeloma
 - Lupus Erythematosus
 - Macroglobulinemia
 - Wegner's Disease
 - Etiology unknown (documented chronic renal failure of at least 6-8 weeks duration)

Retransplantation

Repeat transplant due to acute or chronic graft failure is considered **medically necessary**.

Simultaneous Liver Kidney Transplantation

Kidney transplant as part of a simultaneous liver kidney (SLK) transplantation is considered **medically necessary** when criteria for

liver transplantation are met and when **one** of the following are met:

- The individual has acute renal failure secondary to either hepatorenal syndrome or acute kidney injury; either of which have required at least 6 weeks of dialysis therapy; **or**
- The individual has chronic kidney disease with a measured creatinine clearance of less than or equal to 30cc/min; **or**
- The individual has prolonged acute kidney failure or kidney failure of unknown cause and a renal biopsy showing fixed renal damage.

Not Medically Necessary:

Kidney transplantation for conditions other than end stage renal disease is considered **not medically necessary**.

Kidney transplantation as part of a simultaneous liver kidney (SLK) transplant is considered **not medically necessary**, if *one* of the above SLK criteria is not met.

Note: For multi-organ transplant requests, criteria must be met for each organ requested. In those situations, an individual may present with a concurrent medical condition which may be considered an exclusion or a comorbidity that would preclude a successful outcome, but would be treated with the additional organ transplant. Such cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

General Individual Selection Criteria

In addition to having one of the clinical indications above, the member must not have a contraindication as defined by the American Society of Transplantation in Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation (2001) listed below.*

Absolute Contraindications- for Transplant Recipients include, but are not limited to, the following:

- A. Metastatic cancer
- B. Ongoing or recurring infections that are not effectively treated
- C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery
- D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured
- E. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations
- F. Potential complications from immunosuppressive medications are unacceptable to the patient
- G. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention [CDC] definition of CD4 count, 200cells/mm³) unless the following are noted:
 - 1. CD4 count greater than 200cells/mm³ for greater than 6 months
 - 2. HIV-1 RNA undetectable
 - 3. On stable anti-retroviral therapy greater than 3 months
 - 4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm)
 - 5. Meeting all other criteria for kidney transplantation

*Steinman, Theodore, et al. Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation. Transplantation. 2001; 71 (9):1189-1204.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider

reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

00868	Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; renal transplant (recipient)
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
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

ICD-10 Procedure

0TY00Z0	Transplantation of right kidney, allogeneic, open approach
0TY00Z1	Transplantation of right kidney, syngeneic, open approach
0TY10Z0	Transplantation of left kidney, allogeneic, open approach
0TY10Z1	Transplantation of left kidney, syngeneic, open approach

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Approximately 37 million Americans were reported to have chronic kidney disease (CKD), with nearly 118,000 requiring initiation of treatment for kidney failure known as end stage renal disease (ESRD) each year (CDC, 2021). There was a steady rise in the rate of ESRD from 1980 to 2011; the incident rate of ESRD has started to decline. As of December 2021, the Organ Procurement and Transplantation Network (OPTN) reported that there were 97,958 Americans on the wait list for kidney transplantation and, in 2020, a total of 22,817 kidney transplants were performed (OPTN, 2021). According to data from the OPTN, for individuals receiving primary kidney transplants between 2008 and 2015, the 1-, 3- and 5-year survival rates were 97.1%, 92.9% and 86.3%, respectively.

A kidney transplant involves the removal of a kidney from a deceased or living donor and implantation into a recipient. A donor left kidney is usually transplanted to the right iliac fossa with the renal artery anastomosed end-to-end to the hypogastric artery and the renal vein end-to-side to the common iliac vein. The ureter is implanted into the bladder and (under special conditions) a uretero-ureteral anastomosis or ureteropyelostomy may be performed.

Hepatorenal syndrome is a severe complication of liver cirrhosis or other severe liver disease. Features of hepatorenal syndrome are renal dysfunction caused by abnormalities in the arterial circulation and the vasoactive systems, resulting in renal vasoconstriction and renal insufficiency. There are two types of hepatorenal syndrome. Type I hepatorenal syndrome occurs when renal function is rapidly reduced and has an ominous prognosis which is usually reversed by liver transplantation. Type II hepatorenal syndrome occurs when renal failure does not progress rapidly. It can be quite difficult to distinguish these two conditions in individuals with severe liver disease. Liver transplantation is the recognized treatment for hepatorenal syndrome (Davis, 2005; Marik, 2006).

Concern has been raised since the introduction of the MELD (model for end-stage liver disease) prioritization for liver transplant that some recipients that undergo combined liver and kidney transplantation may have reversible renal failure. To address this issue, the American Society of Transplantation and American Society of Transplant Surgeons met in March 2006 to review post-MELD data on the impact of renal function on liver waitlist and transplant outcomes and the result of simultaneous liver kidney transplantation. This committee issued a consensus statement with regard to simultaneous liver-kidney (SLK) transplantation summarized below (Davis, 2007):

- In the setting of **chronic** kidney disease, a measured creatinine clearance of less than or equal to 30cc/min was considered the appropriate threshold for SLK transplantation.
- In the setting of **acute renal failure** secondary to hepatorenal syndrome or acute kidney injury, renal dysfunction requiring dialysis reflects a decreased capacity for renal recovery and SLK transplantation is considered appropriate. The committee through consensus established a six (6) weeks dialysis duration threshold prior to SLK transplantation.
- In individuals with prolonged acute kidney failure or kidney failure of unknown cause **and** a renal biopsy showing fixed renal damage (e.g. greater than 30-50% glomerulosclerosis, arteriolar hyalinosis, tubular atrophy, interstitial fibrosis) SLK may be medically necessary.
- In the setting of **acute renal failure including hepatorenal syndrome** not requiring dialysis, SLK transplantation was not felt to be medically necessary or appropriate. In reaching this consensus, the committee determined that liver transplant recipients with a glomerular filtration rate (GFR) of less than 30cc/min had a 1-year post-transplant survival of 81.5% and only 25/1648 (1.5%) of these recipients were listed for kidney transplant within a year of liver transplantation.

The 2020 Kidney Disease Improving Clinical Outcomes (KDIGO) clinical practice guideline on evaluation and management of candidates for kidney transplantation, developed by an international group of experts, recommended that individuals with chronic kidney disease who are expected to reach end-state kidney disease be considered for kidney transplantation, except for individuals with the following conditions:

- Multiple myeloma, light chain deposition disease or heavy chain deposition disease unless they have successfully received a curative treatment;
- AL amyloidosis with significant extrarenal involvement;
- Decompensated cirrhosis (these individuals can be considered for SLK);
- Severe irreversible obstructive or restrictive lung disease; and
- Severe uncorrectable symptomatic cardiac disease determined by a cardiologist to preclude transplantation.

In addition, the KDIGO guideline recommends that kidney transplant evaluation be delayed for individuals with the following conditions until they have been satisfactorily managed:

- Unstable psychiatric disorder or current substance abuse disorder that affects decision-making and puts the individual at an unacceptable level of post-transplant risk;

- Ongoing health-compromising behavior;
- Active infection that is not properly treated (excluding hepatitis C);
- Active malignancy other than indolent and low-grade cancers;
- Active symptomatic cardiac disease that has not been evaluated by a cardiologist;
- Active symptomatic peripheral arterial disease;
- Recent stroke or transient ischemic attack;
- Active peptic ulcer disease, diverticulitis, acute pancreatitis, gallstone or gallbladder disease or inflammatory bowel disease;
- Acute hepatitis; or
- Severe hyperparathyroidism.

In 2017, United Network of Organ Sharing (UNOS) implemented policy changes for SLK transplantation based on changes the UNOS/Organ Procurement and Transplant Network (OPTN) board recommended. The decision was made based on subjective criteria to implement the new SLK allocation policy to standardize utilization for SLK. Individuals meeting the SLK allocation policy are defined based on the following criteria: sustained kidney injury with estimated glomerular filtration rate (eGFR) < 60 mL/min for 90 days or more with a final eGFR <30 mL/min. (UNOS, 2022)

Controlled HIV infection is not considered a contraindication to kidney transplant (Chadban, 2020). In 2019, Zheng and colleagues published a meta-analysis of studies on outcomes after kidney transplantation in HIV-positive individuals. The meta-analysis included 27 cohort studies and 1670 case series published between July 2003 and May 2018. The authors found a pooled 1-year survival rate of 97% and a 5-year survival rate of 94%.

Definitions

Allotransplantation: The transfer of cells, tissues, or whole organs from one individual to another within the same species.

Chronic renal disease: The permanent loss of kidney function.

End stage renal disease: Persistent decline in renal function as documented by falling creatinine clearance in an individual diagnosed with a renal disease whose natural history is progression to renal impairment requiring **current or impending** renal replacement (dialysis or transplant).

Nephropathy: Refers to damage or disease of the kidney.

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Peer Reviewed Publications:

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2. Cecka JM. The UNOS Scientific Renal Transplant Registry - 2000. Clin Transpl. 2000:1-18.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Society of Nephrology. Available at: <https://www.asn-online.org/>. Accessed on November 14, 2022.
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3. Organ Procurement and Transplantation Network. National Data. Available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>. Accessed on November 14, 2022.
4. United Network for Organ Sharing. Available at: <http://www.unos.org/>. Accessed on November 14, 2022.
 - Policy 8 Kidney Allocation. Last updated October 27, 2022.
 - Policy 9.9 Liver-Kidney Allocation. Last updated October 27, 2022.

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History

Status	Date	Action
Reviewed	02/16/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, Definitions and References sections.
Revised	02/17/2022	MPTAC review. Clarified MN clinical indication, added note referring to Definition section for additional information on end stage renal disease. Updated Discussion/General Information and References sections.
Reviewed	02/11/2021	MPTAC review. Updated Discussion/General Information and References sections. Reformatted coding section.
Reviewed	02/20/2020	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	03/21/2019	MPTAC review. Updated Discussion/General Information and References sections.

Reviewed	03/22/2018	MPTAC review. Updated Background and References sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Background and References sections.
Reviewed	11/03/2016	MPTAC review. Updated formatting in clinical indications section. Updated references.
Revised	11/05/2015	MPTAC review. Defined abbreviation in both medically necessary and not medically necessary statements. Updated Discussion, References. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Description, Discussion and References.
Reviewed	11/14/2013	MPTAC review. Updated References and Websites.
Reviewed	11/08/2012	MPTAC review. Updated Discussion, References and Websites.
Reviewed	11/17/2011	MPTAC review. Updated References, Coding and Websites.
Revised	11/18/2010	MPTAC review. Clarified Simultaneous Liver Kidney Transplantation medically necessary clinical indication criteria. Updated References and Websites.
Reviewed	11/19/2009	MPTAC review. Place of service removed and references updated.
Reviewed	11/20/2008	MPTAC review. Clarified not medically necessary statement for kidney transplantation as part of a simultaneous liver kidney transplant. References updated.
Revised	11/29/2007	MPTAC review. Added kidney transplantation as part of a simultaneous liver kidney transplant is considered not medically necessary, if any of the above clinical criteria are not met.
Reviewed	08/23/2007	MPTAC review. References updated.
New	09/14/2006	MPTAC review. Document TRANS.00032 converted into a clinical UM guideline.
Reviewed	03/23/2006	MPTAC review. Definitions added. References updated.
Revised	04/28/2005	

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

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his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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