

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023
Next Review Due By: June 2024



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

A successful kidney transplant improves a patient's quality of life and reduces mortality risk for many transplant recipients when compared with patients undergoing maintenance dialysis. Transplant candidates who have no known contraindications should be referred to a transplantation program when the estimated glomerular filtration rate (eGFR) is $<30 \text{ mL / min /1.73 m}^2$. An early referral allows ample time for a complete evaluation and for any required interventions to address relative contraindications prior to transplantation. It also allows time to recruit a living donor. Patients should also be evaluated for the possible presence and severity of heart disease and applicable preoperative interventions should be explored. Patients with a history of cancer should undergo a waiting period of approximately 2-5 years which is free of recurrence prior to transplantation (dependent upon patient and tumor characteristics) (Rossi 2023).

Post-transplantation survival rates vary based upon the source of the allograft, patient age, and the presence and degree of severity of comorbid conditions. Survival rates may also be dependent on sex, race, and degree of immunosuppression. Cardiovascular disease is the leading cause of death among adult kidney allograft recipients. Diabetic patients also report lower survival rates. However, rates are higher than those who undergo dialysis only. Infections are a leading cause of mortality during the early post-transplant period. Causes of death post-transplantation have changed over time and differ with age and are usually attributed to cardiac disease, cancer, and stroke (¹Vella 2023).

The majority of transplants in all age groups in 2022 were kidney transplants. Those awaiting a kidney transplant also comprise the highest number of those on the transplant waiting list (HRSA 2023):

	Transplant Performed	Waiting List
Kidney	25,499	88,901
Liver	9,528	10,625
Heart	4,111	3,365
Lung	2,692	960
Other	950	2,141

The number of kidney transplants increased by 3.36% from 2021 to 2022 compared to 8% from 2020 to 2021 (UNOS 2023).

Children and Adolescents

Kidney transplantation continues to be the standard treatment for children with end-stage renal disease (ESRD). Patient survival is better in pediatric kidney transplant recipients than in adults. Over the last several years, kidney allograft and patient survival have increased along with advances in immunosuppressive therapy. The United States Organ Procurement and Transplantation Network (OPTN) and the United States Scientific Registry of Transplant Recipients (SRTR) published data for graft survival rates in children and adolescents following kidney-only transplantation from both deceased and living donors. For the period of 2014-2016, data from the OPTN and SRTR shows 1-year graft survival for kidney-only transplants from a deceased donor to be 96.9% and 5-year graft survival

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023

Next Review Due By: June 2024



to be 85.2% (OPTN & SRTR 2023). Kidney-only transplants from a living donor for the same period showed 1-year graft survival of 97.6% and 5-year graft survival of 93.1% (OPTN & SRTR 2023). The OPTN and SRTR also published acute rejection rates for 2020. The acute rejection rate for ages 6-11 years was 7.7% and those ages 12-17 years was 11.3%. Mortality remains higher for infants compared with older children. Survival is improved for children (similar to adults) with a kidney allograft compared with those who remain on dialysis. An observational study was conducted that included almost 6000 patients under age 19 who were placed on the kidney transplant waiting list. Additional long-term complications following transplantation in children include hypertension, cardiovascular disease, recurrent infection, malignancy, type 2 diabetes, mineral-bone disorders, surgical sequelae, and recurrence of the primary disease, which affect graft survival (¹McDonald 2022). In the United States, approximately 800 kidney transplants are performed in children below age 18 annually (²McDonald 2022).

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Transplant Evaluation

(¹⁻²Vella 2023; ¹⁻²McDonald 2022; ¹⁻²MCG 2022; AMR 2020; Rossi 2023; DynaMed 2023; DynaMed 2020; KDIGO 2020)

Please see MCP-323 Pre-Transplant Evaluation for additional criteria and information.

Criteria for transplant evaluation include:

1. History and physical examination; **AND**
2. Psychosocial evaluation and clearance:
 - a. No behavioral health disorder by history or psychosocial issues:
 - If history of behavioral health disorder, no severe psychosis or personality disorder;
 - Mood/anxiety disorder must be excluded or treated;
 - Member has understanding of surgical risk and post procedure compliance and follow-up required.
 - AND**
 - b. Adequate family and social support.

AND

3. EKG; **AND**
4. Chest x-ray; **AND**
5. Cardiac clearance in the presence of any of the following:
 - a. Chronic smokers; **OR**
 - b. Members > 50 years age; **OR**
 - c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension or chronic pulmonary disease; **AND**
7. Neurological exam and clearance for transplant including **ONE** of the following:
 - a. Normal neurologic exam; **OR**

Molina Clinical Policy
Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023
Next Review Due By: June 2024



- b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g., diabetic peripheral neuropathy); **OR**
- c. Abnormal neurological exam with positive findings including **ONE** of the following:
 - o Lumbar puncture normal cytology; **OR**
 - o Lumbar puncture with cytological exam abnormal, however central nervous system disease treated prior to clearance.

AND

8. A Performance Status that includes **ONE** of the following:
- a. Karnofsky score 70-100%; **OR**
 - b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

AND

9. Lab studies that include:
- a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
 - b. Serologic screening for: Human Immunodeficiency Virus (HIV); Epstein Barr virus (EBV); Hepatitis B virus (HBV); Hepatitis C virus (HCV); cytomegalovirus (CMV); rapid plasma reagin (RPR) and/or fluorescent treponemal antibody (FTA):*
 - If HIV positive **ALL** of the following must be met:
 - i. CD4 count >200 cells/mm-3 for >6 months; **AND**
 - ii. Human Immunodeficiency Virus 1 (HIV-1) ribonucleic acid undetectable; **AND**
 - iii. On stable anti-retroviral therapy >3 months; **AND**
 - iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
 - c. Urine drug screen if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age \geq 45) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

11. Gynecological examination with Pap smear for women ages \geq 21 to \leq 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy or a total vaginal hysterectomy) within the last three years with complete workup and treatment of abnormal results as indicated.*

Within the last 12 months:

- 1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
- 2. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated; **AND**
- 3. Prostate Specific Antigen (PSA) if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Additional Criteria

In addition, approval of a request for an Adult or Pediatric Pre-Transplant Evaluation for Kidney Transplant must include **ALL** of the following:

- 1. A comprehensive history and physical examination including: a current evaluation of the Member's kidney disease (including (GFR) and dialysis history); past medical history; social history including drug/alcohol use

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023

Next Review Due By: June 2024



- and current smoking status; compliance with the prescribed plan of care; current BMI; current medications; and any current lab or imaging results; **AND**
- Documentation of compliance with dialysis if the Member is on dialysis. This should be provided from the dialysis center. (Member description of dialysis compliance is not adequate to satisfy this criteria); **AND**
 - Documentation of a hemoglobin A1c within target range for Members with diabetes; **AND**
 - For Members with daily cannabis use: documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, **AND** there is documentation of member compliance with a physician prescribed plan of care for prescribed cannabis use; **AND**
 - For Members with a BMI > 35, documentation of compliance with a physician prescribed and managed program of weight loss and a reasonable expectation that the member can achieve a BMI ≤ 35 at the time of transplant.

For members who do not meet **ALL** of the above criteria, office visits with participating providers (including transplant nephrologist, psychosocial providers, endocrinologist, etc.) will be approved. This will facilitate generating the above, medically necessary documentation.

Adult and Pediatric Criteria for Transplantation

Kidney transplantation from a deceased or a living donor is **considered medically necessary** in adult and pediatric Members that have met **ALL** of the following criteria:

- Renal insufficiency with uremia or impending/current ESRD with poor renal function documented by progressive and irreversible deterioration in renal function over the previous 6–12 months and **ONE** of the following:
 - Currently on dialysis; **OR**
 - In adults > 18 years and older, the measured or calculated GFR is < 20 mL/min; **OR**
 - In children younger than age 18, the measured or calculated GFR is < 30 mL/min.

AND

- No genitourinary disease by history and physical:
 - Test results negative; **OR**
 - Treated/minor abnormalities.

AND

- All transplant criteria are met.

AND

- The requesting transplant recipient should not have any of the following **absolute contraindications**:
 - Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
 - Malignant neoplasm with a high risk for recurrence, non-curable malignancy (excluding localized skin cancer); **OR**
 - Systemic and/or uncontrolled infection; **OR**
 - AIDS (CD4 count < 200 cells/mm³); **OR**
 - Unwilling or unable to follow post-transplant regimen as evidenced by **ONE** of the following:
 - Documented history of non-compliance; **OR**
 - Inability to follow through with medication adherence or office follow-up.
- OR**
- Chronic illness with one year or less life expectancy; **OR**
 - Severe irreversible extra renal disease; **OR**
 - Limited, irreversible rehabilitation potential; **OR**
 - Active untreated substance abuse issues (requires documentation supporting that Member is free from addiction for minimally 6 months if previous addiction was present); **OR**

Molina Clinical Policy
Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023
Next Review Due By: June 2024



- j. No adequate social or family support.

AND

5. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
 - a. Smoking, documentation supporting free from smoking for 6 months; **OR**
 - b. Active peptic ulcer disease; **OR**
 - c. Active gastroesophageal reflux disease; **OR**
 - d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
 - e. Obesity with body mass index of >30 kg/m² may increase surgical risk; **OR**
 - f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
 - g. ESRD caused by congenital malformations (e.g., spina bifida, prune belly, vesico-uretreic reflux, bladder extrophy, posterior urethral valve, vertebral/vascular anomalies, anal atresia, tracheo-esophageal fistula, esophageal atresia, renal anomalies/radical dysplasia), acquired malformations (neurogenic, tuberculosis, repeated surgery for vesico-ureteric reflux) or functional disorders of the lower urinary tract; these abnormalities require clearance by urologist with potential surgical correction prior to transplantation; **OR**
 - h. Absent bladder or sphincter insufficiency (e.g., iatrogenic, neurogenic); clearance by a urologist is required with potential suprapubic urinary diversion being performed at least 10-12 weeks prior to consideration of transplantation; **OR**
 - i. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

NOTE: In the event of a request for any of the above relative contraindications, the PCP/requesting physician must provide written documentation outlining knowledge regarding the existence of the contraindication, provide a written explanation of the advantages of surgery, and explain how the advantages outweigh the risks.

Simultaneous Liver-Kidney Transplantation

A simultaneous liver and kidney transplant **may be considered medically necessary** when **ANY** of the following criteria are met as defined by OPTN Policy 9.9:

1. Chronic kidney disease with a measured or calculated GFR less than or equal to 60 mL/min for greater than 90 consecutive days and **ONE** of the following:
 - a. That the candidate has begun regularly administered dialysis as an ESRD patient in a hospital-based, independent non-hospital based, or home setting; **OR**
 - b. At the time of registration on the kidney waiting list, that the candidate's most recent measured or calculated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min; **OR**
 - c. On a date after registration on the kidney waiting list, that the candidate's measured or calculated CrCl or GFR is less than or equal to 30 mL/min.

OR

2. Candidates with sustained acute kidney injury and **ONE** of the following (or a combination of both) of the following, for the last 6 weeks:
 - a. Has been on dialysis at least once every 7 days; **AND/OR**
 - b. Has a measured or calculated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days.

OR

3. Metabolic disease and a diagnosis of at least **ONE** of the following:
 - a. Hyperoxaluria; **OR**
 - b. Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I; **OR**
 - c. Familial non-neuropathic systemic amyloidosis; **OR**
 - d. Methylmalonic aciduria.

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023
Next Review Due By: June 2024



Continuation of Therapy

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation **ALL** of the following information is required for medical review:
 - a. Presence of no absolute contraindication as listed above; **AND**
 - b. History and physical within the last 12 months; **AND**
 - c. Kidney profile within the last 12 months; **AND**
 - d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
 - e. Psychosocial evaluation or update within the last 12 months; **AND**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.
2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
 - a. Authorization letter/documentation from previous insurer; **AND**
 - b. Presence of no absolute contraindication as listed above; **AND**
 - c. History and physical within the last 12 months; **AND**
 - d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
 - e. Psychosocial evaluation or update within the last 12 months; **AND**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

For Members with Significant or Daily Cannabis Use

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
2. If the Member's cannabis use follows a formal, State-based program for managed medical cannabis, the request should include:
 - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
 - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Chaudhry et al. (2022) performed a systematic review and meta-analysis to study the survival benefit of transplantation versus dialysis for waitlisted kidney failure patients with a priori stratification. Online databases were used (e.g., MEDLINE, Ovid Embase, Web of Science, Cochrane Collection, and ClinicalTrials.gov) and included results between database inception and March 1, 2021. This included comparative studies that assessed all-cause mortality for transplantation versus dialysis in patients with kidney failure waitlisted for transplant surgery. In total, 48 observational studies with no randomized controlled trials (n=1,245,850 patients) were used. Overall, 92% of the studies reported a long term (> 1 year) survival benefit related with transplantation compared with dialysis. Eleven studies identified stratum in which transplantation offered no statistically significant benefit over remaining on dialysis. Eighteen studies

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023

Next Review Due By: June 2024



were suitable for meta-analysis with kidney transplantation showing a strong survival benefit. Kidney transplantation remains the standard treatment modality for many patients with kidney failure in effort to reduce all-cause mortality however, some subgroups may lack a survival benefit.

Poggio et al. (2021) report that current short-term kidney post-transplant survival rates are excellent, however long-term outcomes have historically remained unchanged. Data from the national SRTR were evaluated from 1-year and 5-year graft survival and half-lives for kidney transplant recipients in the United States. This included adults over age 18 who received solitary kidney transplants (n = 331,216) between 1995 and 2017. The mean age was 49.4 years, 60% were male, and 25% of the total population were Black. The median survival for deceased donor transplants increased from 8.2 years between 1995 and 1999 to an estimated 11.7 years in the most recent era. Living kidney donor transplant median survival increased from 12.1 years between 1995 and 1999 to 19.2 years for transplants performed between 2014 and 2017. Data show steady improvement in long-term outcomes with notable improvement among higher-risk subgroups. This suggests a smaller gap for those disadvantaged after transplantation.

Rodrigues et al. (2019) performed a retrospective observational study that included records of patients who received a living donor kidney transplant (LDKT) between January 1, 2004, to December 31, 2017. Data were compared to deceased donor transplantation. The purpose of the study was to assess graft survival in a population of LDKT in the last 14 years as well as the potential impact of some clinical features. Survival data were evaluated by Kaplan-Meier, log rank test, and Cox regression. A total of 277 LDKTs were performed and median follow-up time was 4 years. Graft loss was detected in 9% of patients and 4 patients died. Overall survival was 97% at year 1, 94% at year 5, and 83% at years 10 and 13. Graft survival was considerably worse in those with early vascular complications that required surgical intervention as well as in female recipients. The authors observed a good overall graft survival (>80% after 13 years). Early vascular complications, HLA mismatches, rejection, and female recipients were factors related to poor outcomes.

Thongprayoon et al. (2020) report that while advances in surgical, immunosuppressive, and monitoring protocols have led to substantial improvement of overall one-year kidney allograft outcomes, significant change has not been found in long-term kidney allograft outcomes. Failure of kidney allografts are contributed to chronic and acute antibody-mediated rejection (ABMR) and non-immunological complications. This includes multiple incidences of primary kidney disease, cardiovascular diseases, infections, and malignancy. Current research is focused on the use of molecular techniques to enhance histological diagnostics and noninvasive surveillance. Innovative approaches are being used more frequently to discover immunosuppressive methods to overcome critical sensitization, prevent the development of anti-human leukocyte antigen (HLA) antibodies, treat chronic active ABMR, and reduce non-immunological complications following kidney transplantation. This includes the recurrence of primary kidney disease and other complications (e.g., cardiovascular diseases, infections, and malignancy). The utilization of electronic health records will further aid research to yield more data. Telemedicine is another field that has grown – for example, kidney transplant patients living in remote areas can be reached and ensuring that scarce healthcare resources are more accessible for kidney transplantation. Noninvasive monitoring and the improvement of histological diagnostics (with the aid of molecular techniques) offer creative means to identify immunosuppressive agents. This discovery can overcome critical sensitization, prevent the creation of anti-HLA antibodies, treat chronic active ABMR, and reduce non-immunological complications following transplantation (e.g., recurrence of primary kidney disease, cardiovascular diseases, infections, and malignancy).

Children and Adolescents

Francis et al. (2020) report that survival among pediatric kidney transplant recipients has improved over the past five decades however, changes in cause-specific mortality remain uncertain. The authors performed a retrospective cohort study to estimate the link between transplant era and overall and cause-specific mortality for the child and adolescent population. Data included those under age 20 and who received the first kidney transplant between 1970 and 2015 from the Australian and New Zealand Dialysis and Transplant Registry. A total of 1810 recipients were included. The median age at transplantation was 14 years. Approximately 58% of recipients were male, and 52% received a kidney from a living donor. Recipients were followed for a median of 13.4 years. Twenty-four percent of the recipients followed died (431) with 174 from cardiovascular causes, 74 from infection, 50 from cancer, and 133 from other causes. Survival rates increased over time with 5-year survival rates rising from 85% for those first transplanted in 1970-1985 to 99% between 2005-2015. Increased survival was primarily contributed to a decrease in deaths from cardiovascular causes and infections. In comparison with patients transplanted between 1970-1985, mortality risk was 72% lower among those transplanted 2005-2015.

Molina Clinical Policy
Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023
 Next Review Due By: June 2024



National and Specialty Organizations

The **European Association of Urology (EAU)** published guidelines for renal transplantation. EAU recommendations include organ retrieval and preservation prior to transplantation, living and deceased donor implantation surgery, including anesthetic, pre-, intra-, and post-operative management, surgical approaches for first, second, third, and further transplants, donor and recipient complications, immunosuppression, and follow-up after transplantation. Each recommendation is assigned a “strong” or “weak” rating based on available evidence (EAU 2023).

KDIGO (Kidney Disease: Improving Global Outcomes) published *Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation*. Recommendations are outlined for immunosuppression, graft monitoring, as well as prevention and treatment of infection, cardiovascular disease, malignancy, and other complications that are common in kidney transplant recipients, including hematological and bone disorders. There are also pediatric-specific guidelines. The KDIGO guideline also outlines prevention and treatment of complications that may follow kidney transplantation (KDIGO 2020).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	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	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

HCPCS (Healthcare Common Procedure Coding System) Code

HCPCS	Description
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and Rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023

Next Review Due By: June 2024



APPROVAL HISTORY

6/14/2023	Policy reviews, changes to criteria include: "Pre-Transplant Evaluation" changed to "Transplant Evaluation," new criteria 7b, removal of abnormal serology criteria from new criteria 8b, new criteria 9 changed to age 45 years, and asterisk added to pre-transplant criteria 11 to denote it may be waived by a Center of Excellence. Overview, Summary of Medical Evidence, and References sections updated. "Marijuana" changed to "cannabis." Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Supplemental Information section and ICD-10 codes removed. Updated code description for code 50547. IRO Peer Review on May 24, 2023, by a practicing, board-certified physician with a specialty in Surgery Transplant.
6/8/2022	Policy reviewed, no changes to criteria; included section on marijuana use; updated Overview, Summary of Medical Evidence and Reference sections.
6/9/2021	Policy reviewed, no changes, updated references.
4/23/2020	Policy reviewed, updated criteria for simultaneous liver and kidney transplant based on OPTN Policy 9.9. Guidelines and references updated. Removed the CPT code 50380.
9/13/2018 & 9/18/2019	Policy reviewed, no changes.
12/13/2017	Policy reviewed, changed the age for pediatric criteria to younger than 18 years of age (from 12) and updated professional guidelines and references.
12/16/2015, 9/15/2016 & 9/19/2017	Policy reviewed, no changes.
11/20/2014	Policy reviewed; updated the pretransplant and transplant criteria.
1/14/2013	Policy reviewed, no changes
8/20/2012	Pretransplant evaluation criteria added; adult and pediatric criteria changed; contraindications section changed, added criteria for simultaneous liver-kidney transplantation, professional guidelines updated.
10/26/2011	Policy reviewed, no changes.
2/28/2008	New policy.

REFERENCES

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified). Accessed May 22, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
- Chaudhry D, Chaudhry A, Peracha J, Sharif A. Survival for waitlisted kidney failure patients receiving transplantation versus remaining on waiting list: systematic review and meta-analysis. *BMJ*. 2022 Mar 1;376:e068769. doi: 10.1136/bmj-2021-068769. PMID: 35232772; PMCID: PMC8886447.
- DynaMed. Overview of chronic kidney disease (CKD) in adults (record no. T115336). Updated March 11, 2023. Accessed May 22, 2023. www.dynamed.com.
- DynaMed. Chronic kidney disease (CKD) in children (record no. T908705). Updated April 8, 2022. Accessed May 22, 2023. www.dynamed.com.
- European Association of Urology (EAU). Guidelines on renal transplantation. Published March 2023. Accessed May 23, 2023. <https://uroweb.org/guidelines/renal-transplantation>.
- Francis A, Johnson DW, Melk A, Foster BJ, Blazek K, Craig JC, Wong G. Survival after Kidney Transplantation during Childhood and Adolescence. *Clin J Am Soc Nephrol*. 2020 Mar 6;15(3):392-400. doi: 10.2215/CJN.07070619. Epub 2020 Feb 19. PMID: 32075809; PMCID: PMC7057311.
- Health Resources and Services Administration (HRSA). Organ donation statistics. Updated March 2023. Accessed May 23, 2023. <https://www.organdonor.gov/learn/organ-donation-statistics>.
- Kidney Disease: Improving Global Outcomes (KDIGO). Clinical practice guidelines on the evaluation and management of candidates for kidney transplantation. Published April 2020. Accessed May 23, 2023. <https://kdigo.org/guidelines/transplant-candidate/>.
- ¹ McDonald RA. Kidney transplantation in children: Outcomes. Updated January 3, 2022. Accessed May 22, 2023. www.uptodate.com.
- ² McDonald RA. Kidney transplantation in children: General principles. Updated January 3, 2022. Accessed May 22, 2023. www.uptodate.com.
- ¹ MCG. Inpatient and surgical care: Renal transplant (S-1015) [26th ed.]. Updated September 1, 2022.
- ² MCG. Inpatient and surgical care: Renal transplant, pediatric (P-1015) [26th ed.]. Updated September 1, 2022.
- Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2021 annual data report: Kidney. Published February 2023. Accessed May 23, 2023. https://srtr.transplant.hrsa.gov/annual_reports/2021/Kidney.aspx.
- Poggio ED, Augustine JJ, Arrigain S, Brennan DC, Schold JD. Long-term kidney transplant graft survival-Making progress when most needed. *Am J Transplant*. 2021 Aug;21(8):2824-2832. doi: 10.1111/ajt.16463. Epub 2021 Feb 8. PMID: 33346917.
- Rodrigues S, Escoli R, Eusébio C, Dias L, Almeida M, Martins LS, Pedrosa S, Henriques AC, Cabrita A. A Survival Analysis of Living Donor Kidney Transplant. *Transplant Proc*. 2019 Jun;51(5):1575-1578. doi: 10.1016/j.transproceed.2019.01.047. Epub 2019 Jan 21. PMID: 31155195.
- Rossi A. Kidney transplantation in adults: Evaluation of the potential renal transplant recipient. Updated March 3, 2023. Accessed May 22, 2023. www.uptodate.com.
- Thongprayoon C, Hansrivijit P, Leeaphorn N, Acharya P, Torres-Ortiz A, Kaewput W, Kovvuru K, Kanduri SR, Bathini T, Cheungpasitporn W. Recent Advances and Clinical Outcomes of Kidney Transplantation. *J Clin Med*. 2020 Apr 22;9(4):1193. doi: 10.3390/jcm9041193. PMID: 32331309; PMCID: PMC7230851.

Molina Clinical Policy
Kidney Transplantation: Policy No. 045

Last Approval: 6/14/2023

Next Review Due By: June 2024



18. United Network for Organ Sharing (UNOS). Data and transplant statistics. Updated May 20, 2023. Accessed May 22, 2023. <https://unos.org/data/>.
19. ¹Vella J. Kidney transplantation in adults: Patient survival after kidney transplantation. Updated May 9, 2023. Accessed May 22, 2023. www.uptodate.com.
20. ²Vella J. Kidney transplantation in adults: Risk factors for graft failure. Updated January 19, 2023. Accessed May 22, 2023. www.uptodate.com.