

Molina Clinical Policy

Kidney Transplantation: Policy No. 045

Last Approval: 6/8/2022

Next Review Due By: June 2023



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 a majority of 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 mL / min /1.73 m². 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 live donor. Patients should also be evaluated for the possible presence and severity of heart disease; applicable preoperative interventions should be explored. Patients with cancer history should undergo a waiting period which is free of recurrence, approximately two to five years prior to transplantation (dependent upon patient and tumor characteristics). (Rossi, 2020).

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 have changed over time and differ with age. Deaths are usually attributed to cardiac disease, cancer, and stroke appear to have increased. (Vella, 2021).

Among transplant recipients in 2021 of all ages, the majority were kidney. Those awaiting a kidney transplant also comprise the highest number of those on the transplant waiting list (HRSA, 2022):

	Transplant Performed	Waiting List
Kidney	24,670	90,483
Liver	9,236	11,891
Heart	3,817	3,502
Lung	2,524	1,051
Other	1,108	290

Among transplants by organ type between 2020 and 2021, kidney transplants increased by 8% as compared to other organ transplants that increased by 3-6% (liver, heart, pancreas and intestine) (UNOS, 2022).

Children and Adolescents

Kidney transplantation continues to be the standard treatment for children with end-stage kidney disease (ESKD). 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. A study based on data from the United States Scientific Registry of Transplant Recipients (SRTR) shows that improvements of one-year graft survival for transplants performed in 1987 versus 2010 (81 versus 97 percent), five-year graft survival for transplants performed in 1987 versus 2006 (59 versus 78 percent), and 10-year graft survival for transplants performed in 1987 versus 2001 (47 versus 60 percent). Mortality remains higher for infants compared with older children. Survival

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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. (¹ McDonald, 2022). In the United States, approximately 800 kidney transplants are performed in children below age 18 annually. (² McDonald, 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.

Pre-Transplant Evaluation

(Vella, 2022; ¹⁻² McDonald, 2022; ¹⁻² MCG, 2021; Vella, 2021; AMR, 2020; Rossi, 2020; ¹⁻² DynaMed, 2018; KDIGO, 2017; Kasiske et al., 2010; KDIGO, 2009)

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 (PAH) or chronic pulmonary disease; **AND**
7. Neurological exam and clearance for transplant including **ONE** of the following:
 - Normal exam by H&P; **OR**
 - Abnormal neurological exam with positive findings including **ONE** of the following:
 - Lumbar puncture normal cytology; **OR**
 - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance.

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AND

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

AND

9. Lab studies that include:
- 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);*
 - Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
 - If HIV positive **ALL** of the following must be met:
 - CD4 count >200 cells/mm³ for >6 months; **AND**
 - HIV-1 RNA undetectable; **AND**
 - On stable anti-retroviral therapy >3 months; **AND**
 - No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
 - If abnormal serology, need physician plan to address and/or treatment as indicated.
 - Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
 - Ceruloplasmin, α 1-antitrypsin phenotype
 - Alpha-fetoprotein
 - Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age ≥ 50) 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 ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

- 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**
 - Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;*
- AND**
- 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:

- 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 and current smoking status; compliance with the prescribed plan of care; current BMI; current medications; and any current lab or imaging results; **AND**

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2. 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**
3. Documentation of a hemoglobin A1c within target range for Members with diabetes; **AND**
4. For Members with daily marijuana use: documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from marijuana use during the transplant and immediate post-transplant time period. Daily marijuana use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical marijuana use and transplants, **AND** there is documentation of member compliance with a physician prescribed plan of care for prescribed marijuana use; **AND**
5. 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 don't meet **ALL** of the above criteria, office visits with transplant 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:

1. Renal insufficiency with uremia or impending/current end stage renal disease (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:
 - a. Currently on dialysis; **OR**
 - b. In adults > 18 years and older, the measured or calculated glomerular filtration rate < 20 mL/min; **OR**
 - c. In children younger than age 18, the measured or calculated glomerular filtration rate < 30 mL/min.

AND

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

AND

3. All pre-transplant criteria are met.

AND

4. The requesting transplant recipient should not have any of the following **absolute contraindications**:
 - a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
 - b. Malignant neoplasm with a high risk for recurrence, non-curable malignancy (excluding localized skin cancer); **OR**
 - c. Systemic and/or uncontrolled infection; **OR**
 - d. AIDS (CD4 count < 200 cells/mm³); **OR**
 - e. 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**
 - f. Chronic illness with one year or less life expectancy; **OR**
 - g. Severe irreversible extra renal disease; **OR**
 - h. Limited, irreversible rehabilitation potential; **OR**
 - i. Active untreated substance abuse issues (requires documentation supporting that Member is free from addiction for minimally 6 months if previous addiction was present); **OR**
 - j. No adequate social or family support.

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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 $>30 \text{ kg/m}^2$ 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 (CKD) with a measured or calculated glomerular filtration rate (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 end-stage renal disease (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.

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

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 strata in which transplantation offered no statistically significant benefit over remaining on dialysis. Eighteen studies

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were suitable for meta-analysis; kidney transplantation showed 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 Scientific Registry of Transplant Recipients (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; median follow-up time was 4 years. Graft loss was detected in 9% of patients; 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 (EHRs) 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 age 14; 58% were male; 52% living donor. Recipients were followed for a median of 13.4 years. Twenty-four percent of the recipients followed died (431) died; 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.

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National and Specialty Organizations

KDIGO (Kidney Disease: Improving Global Outcomes) (2009) published *Clinical Practice Guideline for the Care of Kidney Transplant Recipients*. 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. The KDIGO guideline outlines prevention and treatment of complications that may follow kidney transplantation (the guideline does not discuss pretransplant care). Highlights of the recommendations include the following topics (Kasiske et al., 2010):

1. Induction Therapy
2. Initial Maintenance Immunosuppressive Medications
3. Long-Term Maintenance Immunosuppressive Medications
4. Monitoring Immunosuppressive Medications
5. Treatment of Acute Rejection
6. Treatment of Chronic Allograft Injury
7. Monitoring Kidney Allograft Function
8. Kidney Allograft Biopsy
9. Recurrent Kidney Disease
10. Preventing, Detecting, And Treating Nonadherence
11. Managing Cancer with Reduction of Immunosuppressive Medication
12. Transplant Bone Disease
13. Hematological Complications

Additional information for Providers from AST and KDIGO can be found below:

- American Society of Transplantation (2009) – *Guidelines for Post-Kidney Transplant Management in the Community Setting* (available [here](#))
- KDIGO (2017) – *Managing Your Adult Patients Who Have a Kidney Transplant* (available [here](#))

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT 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

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50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laparoscopic donor nephrectomy (including cold preservation), from living donor

HCPCS 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

ICD-10 Codes

ICD-10	Description
N18.4	Chronic kidney disease Stage 4 severe
N18.5	Chronic kidney disease Stage 5
N18.6	End stage renal disease

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.

APPROVAL HISTORY

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

Government Agencies

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified). Available from [CMS](#). Accessed May 5, 2022.
- Health Resources and Services Administration (HRSA). Organ donation statistics. Available from [HRSA](#). Updated March 2022. Accessed May 5, 2022.

Evidence Based Reviews and Publications

- AMR Peer Review. Policy reviewed in January 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Nephrology.
- ¹ DynaMed. Overview of chronic kidney disease (CKD) in adults (record no. T115336). Available from [DynaMed](#). Updated November 30, 2018. Accessed May 5, 2022. Registration and login required.
- ² DynaMed. Chronic kidney disease (CKD) in children (record no. T908705). Available from [DynaMed](#). Updated November 30, 2018. Accessed May 5, 2022. Registration and login required.
- ¹ MCG. Inpatient and surgical care: Renal transplant (S-1015), 25th ed. Available from [MCG](#). Updated June 7, 2021. Accessed May 5, 2022. Registration and login required.
- ² MCG. Inpatient and surgical care: Renal transplant, pediatric (P-1015), 25th ed. Available from [MCG](#). Updated June 7, 2021. Accessed May 5, 2022. Registration and login required.

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6. ¹ McDonald RA. Kidney transplantation in children: Outcomes. Available from [UpToDate](#). Updated January 3, 2022. Accessed May 5, 2022. Registration and login required.
7. ² McDonald RA. Kidney transplantation in children: General principles. Available from [UpToDate](#). Updated January 3, 2022. Accessed May 5, 2022. Registration and login required.
8. Rossi A. Kidney transplantation in adults: Evaluation of the potential renal transplant recipient. Available from [UpToDate](#). Updated February 19, 2020. Accessed May 5, 2022. Registration and login required.
9. Vella J. Kidney transplantation in adults: Risk factors for graft failure. Available from [UpToDate](#). Updated September 16, 2020. Accessed May 5, 2022. Registration and login required.
10. Vella J. Kidney transplantation in adults: Patient survival after kidney transplantation. Available from [UpToDate](#). Updated June 21, 2021. Accessed May 5, 2022. Registration and login required.

National and Specialty Organizations

1. American Society of Transplantation (AST). Guidelines for post-kidney transplant management in the community setting. Available from [AST](#). Approved 2009. Accessed May 5, 2022.
2. Kasiske BL, Zeier MG, Chapman JR, Craig JC, Ekberg H, Garvey CA, et al. KDIGO clinical practice guideline for the care of kidney transplant recipients: A summary. *Kidney Int.* 2010 Feb;77(4):299-311. doi: 10.1038/ki.2009.377. Accessed May 5, 2022.
3. Kidney Disease: Improving Global Outcomes (KDIGO). Managing your adult patients who have a kidney transplant. Available from [KDIGO](#). Published 2017. Accessed May 5, 2022.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Transplant.* 2009 Nov;9 Suppl 3:S1-155. doi: 10.1111/j.1600-6143.2009.02834.x. Published 2009. Accessed May 5, 2022.
5. United Network for Organ Sharing (UNOS). Transplant trends. Available from [UNOS](#). Updated 2022. Accessed May 5, 2022.

Peer Reviewed Publications

1. 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. Accessed May 5, 2022.
2. 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. Accessed May 5, 2022.
3. 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.
4. Rodrigues S, Escoli R, Eusébio C, Dias L, Almeida M, Martins LS, et al. A survival analysis of living donor kidney transplant. *Transplant Proc.* 2019 Jun;51(5):1575-1578. doi: 10.1016/j.transproceed.2019.01.047. Accessed May 5, 2022.
5. Thongprayoon C, Hansrivijit P, Leeaphorn N, Acharya P, Torres-Ortiz A, Kaewput W, et al. Recent advances and clinical outcomes of kidney transplantation. *J Clin Med.* 2020 Apr 22;9(4):1193. doi: 10.3390/jcm9041193. Accessed May 5, 2022.

APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.