Molina Clinical Policy
Kidney Transplantation: Policy No. 045
Last Approval: 06/12/2024
Next Review Due By: June 2025

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

End Stage Renal Disease (ESRD) is the irreversible final stage of chronic kidney disease, in which the kidneys are unable to function on their own, affecting approximately 500,000 people in the United States (Hashmi et al. 2023). Chronic kidney disease (CKD), defined as renal functional abnormality for three or more months, is most commonly caused by uncontrolled hypertension and/or diabetes, and glomerulonephritis in adults. Approximately 70% of children and adolescents with CKD will progress to ESRD by age 20 years, with the prevailing causes of CKD in children and adolescents being congenital renal and urinary tract abnormalities, and glomerular disease. CKD is staged based off assessed kidney function via disease cause, estimated glomerular filtration rate (GFR), and urinary albumin to creatinine ratio. CKD and ESRD are accompanied by many complications that severely impact quality of life and lead to premature mortality. Treatments of CKD and ESRD include medications, dietary modifications, dialysis, and solid organ transplant ([1-2]DynaMed 2024).

Kidney Transplants, via either living or deceased donors, were most of all transplants in 2023 with a total of 20,440 recipients; and the largest cohort, thirty-three thousand six hundred and fifty-nine patients, awaiting solid organ transplant as of October 2023 (HRSA 2024). Transplant candidates who have no known contraindications should be referred to a transplantation program when the estimated GFR is <30 mL / min /1.73 m2, as an early referral allows ample time for a complete evaluation and for any required interventions to address relative contraindications prior to transplantation.

Kidney transplantation continues to be the standard treatment for children with ESRD. Patient survival is better in pediatric kidney transplant recipients than in adults; however, a successful kidney transplant improves all patients' quality of life and reduces mortality risk for many transplant recipients when compared with patients undergoing maintenance dialysis. Among those who received a living donor kidney transplant between 2015-2017, the adult five-year post-transplant graft survival rate was 80.8% in patients 65 years and older, and 90% in patients aged 18 -34 years. Those who received a deceased donor kidney transplant between 2015-2017, the adult five-year post-transplant graft survival rate was 67.8% in patients 65 years and older, and 81.4% in patients aged 18 - 34 years. In the pediatric population, children aged 0 – 17 years, between the years of 2015 -2017 the five-year patient survival rate in those who received a deceased donor kidney transplant among was 97.1% with little variability by age (Lentine et al. 2022).

Kidney Transplant Allocation Process

Currently transplant candidates are assessed via a complex system of scores that signal health status, estimated medical urgency, time to hospital, registry waiting time, and more. All registrants are assigned a kidney allocation score which signals health condition and medical need based on a variety of factors, such as GFR, dialysis duration, co-morbidities, and more. Adults are assigned an Estimated Post Transplant Survival score ([1]OPTN 2024).

The United Network for Organ Sharing (UNOS) is currently developing a continuous distribution process for kidney and pancreas transplants. The continuous distribution framework gives candidates a composite score which more accurately reflects their status, instead of the current method which heavily relies on categories and sometimes misses candidates in dire need and ensures no single factor/category determines priority for organs. The kidney and pancreas continuous distribution process is in its final stages of approval before implementation ([2]OPTN 2024).

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.

Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant evaluation criteria that must be met prior to solid organ transplant.

Adult and Pediatric Criteria for Kidney Transplantation

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

1. All MCP 459 pre-transplant and transplant evaluation criteria are met
2. 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
   b. In adults 18 years and older: the measured or calculated GFR is < 20 mL/min
   c. In children less than 18 years old: the measured or calculated GFR is < 30 mL/min
3. Absence of genitourinary disease by history and physical, with negative test results and/or minor abnormalities treated
4. The requesting transplant recipient is carefully evaluated and potentially treated for any of the following organ-specific contraindications that apply in addition to the contraindications found in MCP 459:
   a. ESRD caused by congenital malformations (e.g., spina bifida, prune belly, vesicoureteral reflux, vertebral/vascular anomalies, anal atresia), acquired malformations (neurogenic, tuberculosis, repeated surgery for vesicoureteral reflux), or functional disorders of the lower urinary tract, requires clearance by urologist with potential surgical correction prior to transplantation
   b. Bladder or sphincter insufficiency (e.g., iatrogenic, neurogenic), requires clearance by a urologist with potential supravesical urinary diversion being performed at least 10-12 weeks prior to consideration of transplantation

Adult and Pediatric Criteria for Simultaneous Liver-Kidney Transplantation

A simultaneous liver and kidney transplant **may be considered medically necessary** when **ANY** of the following criteria are met in addition to the above kidney transplantation indications:

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. Member has begun regularly administered dialysis as an ESRD patient
   b. At the time of registration on the kidney waiting list, the candidate's most recent measured or calculated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min
   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

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

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

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 stratums in which transplantation offered no statistically significant benefit over remaining on dialysis. Eighteen studies 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 an effort to reduce all-cause mortality. However, some subgroups may lack a survival benefit.

Dharia et al. (2022) conducted a single center observational retrospective cohort study of kidney transplant recipients between 2006 – 2018. The clinicians compared outcomes in transplant recipients with deceased donor recipients with potential but non-actualized living donors to those recipients with actualized living donors, and to deceased donor recipients without potential living donors. A total of 453 kidney transplant recipients were analyzed. Deceased donor recipients without potential living donors and non-actualized living donors did not differ in key donor organ characteristics. The 5-year death censored graft survival of non-actualized living donors was similar to actualized living donors ($p = 0.19$). Deceased donor recipients without potential living donors graft survival were inferior to actualized living donors ($p = 0.005$), but also trended inferior to non-actualized living donors ($p = 0.052$). By multivariate Cox regression analysis, living donor demonstrated similar 5-year graft survival to non-actualized living donors (HR for graft loss 0.8 [95% CI 0.25–2.6], $p = 0.72$) but actualized living donors graft survival was superior to deceased donor recipients without potential living donors (HR 0.34 [0.16–0.72], $p = 0.005$). The authors summarized that deceased donor recipients with potential but non-actualized living donors exhibit similar mid-term graft and patient survival compared to living donor recipients, thus having an identified living donor at the time of pre-transplant assessment portends a favorable prognosis for the recipient.

Hariharan et al. (2021) published a comprehensive review on long term survival after kidney transplantation. The review analyzed from 1996 to 2019, and highlighted the increase in survival rates since 2008 compared to the 90's and early 00's. The article points out that the opioid epidemic contributed to a rise in deceased donor kidneys, but that demand for kidneys has outpaced any increase in supply over the last couple of decades. The leading causes of transplant graft failure in the first year are due to technical issues/vascular complications (41%), acute rejection (17%), and glomerulonephritis (3%); after the first year the leading causes of graft failure are chronic rejection (63%) and glomerulonephritis (6%). The primary causes of death in recipients with functional grafts were cardiovascular disease (31% of deaths), infection (31%), and cancer (7%) in the first-year post-transplant; and cancer (29%), cardiovascular disease (23%), and infection (12%) after the first year. The United States reports lower 5-year survival rates than other countries. Five-year graft survival rates in 2014 for primary kidney transplants from deceased donors and living donors in the United States were 72% and 85%, respectively, as compared with 81% and 90% in Australia and New Zealand,

79% and 87% in Europe, and 81 and 91% in Canada. The article points out that this may be in part due to United States insurance coverage issues for long term immunosuppressive medications, which will hopefully improve after the passage of the Immunosuppressive Drug Coverage for Kidney Transplant Patients Act (Immuno Bill, H.R. 5534) in 2020, which stipulates lifelong coverage for transplant recipients. The article summarized that kidneys from deceased donors with high scores on the Kidney Donor Profile Index have been associated with an increased incidence of delayed graft function, which can be improved by reducing the severity of perfusion injury with a shorter cold ischemia time, as these organs are still vital for recipients with anticipated shorter life spans. The article continues to analyze acute rejection and summates that acute rejection is the result of suboptimal immunosuppressive therapy, particularly in transplant recipients at high immunologic risk, nonadherence to immunosuppressive therapy, or a reduction in immunosuppressive medications. The authors emphasize that prevention of acute rejection with comprehensive screening and care plans is pivotal, as well as infection prevention via vaccinations and patient education. The authors emphasized that efforts to improve graft survival rates will be due to comprehensive care by trained professionals that focus on organ quality and the prevention and treatment of acute rejection, cardiovascular disease, infection, and cancer.

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.

National and Specialty Organizations

The **European Association of Urology (EAU)** (2024) 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. The 2024 publication was a full content update to be fully congruent with current literature.

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).

The **Organ Procurement and Transplantation Network (OPTN)** published *Policy 8: Allocation of Kidneys* which includes adult and pediatric scoring tools, updated requirements, adult and pediatric status exceptions, and more information pertaining to the allocation of kidneys ([1]OPTN 2024).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of

	adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
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

Code	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.

APPROVAL HISTORY

06/12/2024	Policy reviewed. Coverage criteria revised with removal of transplant evaluation, continuation of therapy, and general contraindication coverage criteria as it is now stipulated in MCP 459 Pre-Transplant and General Transplant Evaluation. IRO Peer Reviewed on May 1, 2024, by a practicing physician board certified in Nephrology and Internal Medicine. Specialty society guidelines updated.
04/10/2024	Removed requirement of dialysis center documentation for dialysis compliance. Annual review scheduled for June 2024.
06/14/2023	Policy reviews, changes to criteria include: “Pre-Transplant Evaluation” changed to “Transplant Evaluation,”. Changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria and additional disease processes to criteria, removal of abnormal serology criteria and daily cannabis use section, and addition of asterisk added to pre-transplant criteria to denote it may be waived by a Center of Excellence. “Marijuana” changed to “cannabis.” IRO Peer Review on May 24, 2023, by a practicing, board-certified physician with a specialty in Surgery Transplant.
06/08/2022	Policy reviewed, no changes to coverage criteria; included section on marijuana use.
06/09/2021	Policy reviewed, no changes, updated references.
04/23/2020	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.
09/18/2019	Policy reviewed, no changes.
09/13/2018	Policy reviewed, no changes.
12/13/2017	Policy reviewed, changed the age for pediatric criteria from 12 to younger than 18 years of age.
09/15/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
11/20/2014	Policy reviewed; updated the pretransplant and transplant criteria.
01/14/2013	Policy reviewed, no changes.
08/20/2012	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.
02/28/2008	New policy.

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