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Contents

DISCLAIMER	1
Description of Procedure/Service/Pharmaceutical.....	1
CLINICAL CRITERIA RECOMMENDATION	2
Continuation of Therapy	5
Summary of Medical Evidence.....	6
Coding Information.....	6
References.....	7
REVIEW/REVISION HISTORY	9

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Kidney transplantation is a surgical procedure performed to remove a healthy functioning kidney from a living or brain-dead donor and surgically attaching it into an individual diagnosed with irreversible end stage renal disease or chronic renal failure. End stage renal disease occurs when kidneys are damaged from a disorder, disease or a congenital condition. The kidneys' ability to function properly is impaired. The kidneys ability to properly remove and filter fluid and waste from the body and regulate specific chemicals in the bloodstream is impaired. Non-functioning kidneys may or may not be removed during the procedure. Generally, the nonfunctioning kidneys are left in place and the transplanted kidney is surgically attached in a different location near the nonfunctioning kidney(s); this process decreases the potential

for surgical morbidity. The existing nonfunctioning kidneys are removed if persistent infection, hypertension or interference with the new organ is experienced.

CLINICAL CRITERIA RECOMMENDATION 2-5 29-33

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 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.

Members must meet UNOS guidelines for transplantation and the diagnosis must be made by a Nephrologist and or Transplant Surgeon.

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

Criteria for pretransplant evaluation include all of the following:

- ☐ History and physical examination
- ☐ Psychosocial evaluation and clearance:
 - 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
 - Adequate family and social support
- ☐ EKG
- ☐ Chest x-ray
- ☐ Cardiac clearance in the presence of any of the following:
 - chronic smokers
 - > 50 years age
 - those with a clinical or family history of heart disease or diabetes
- ☐ Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease
- ☐ Lab studies:
 - *Complete blood count, Kidney profile (blood urea nitrogen, creatinine), electrolytes, calcium, phosphorous, albumin, liver function tests, Coagulation profile (prothrombin time, and partial thromboplastin time)
 - *Serologic screening for HIV, Epstein Barr virus (EBV), Hepatitis virus B (HBV), and Hepatitis C (HCV), cytomegalovirus (CMV), RPR and/or FTA:
 - If HIV positive all of the following are met:
 - CD4 count >200 cells/mm-3 for >6 months
 - HIV-1 RNA undetectable
 - On stable anti-retroviral therapy >3 months
 - 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 plans to address and/or treatment as indicated
 - UDS (urine drug screen) if patient is current or gives a history of past drug abuse

- ☐ *Colonoscopy (if indicated or if patient is 50 ≥ older should have had an initial screening colonoscopy, after initial negative screening requires follow up colonoscopy every ten years) with complete workup and treatment of abnormal results as indicated
- ☐ *GYN examination with Pap smear for women ≥21 to ≤ 65 years of age or indicated (not indicated in women who have had a TAH or TVH) with in the last three year with complete workup and treatment of abnormal results as indicated
- ☐ Bladder biopsy indicated if bladder fibrosis or cancer is suspected
- ☐ Ultrasonography (abdomen and pelvis including kidneys, and ureters,), if abnormal additional studies may be necessary in the following order:
 - voiding cystourethrogram
 - cystoscopy
 - retropyelography
 - renal CT

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

AND

Approval of a request for an Adult or Pediatric Pre-transplant Evaluation for **Kidney Transplant** include all of the following: [ALL]

- ☐ A comprehensive history and physical examination including: a current evaluation of the member's kidney disease (including GFR, 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, any current lab or imaging results.
- ☐ 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.
- ☐ Documentation of a hemoglobin A1c within target range for members with diabetes.
- ☐ 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.
- ☐ 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^{2-5 29-33}

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 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:
 - ☐ Currently on dialysis; OR
 - In adults or are 18 years and older: the measured or calculated glomerular filtration rate < 20 mL/min ; OR
 - In children who are younger than 18 years the measured or calculated glomerular filtration rate < 30 mL/min; AND
- ☐ No genitourinary disease by history and physical
 - Test results negative
 - Treated/minor abnormalities; and
- ☐ All pre-transplant criteria are met

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
- ☐ Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer)
- ☐ Systemic and/or uncontrolled infection
- ☐ AIDS (CD4 count < 200cells/mm³)
- ☐ Unwilling or unable to follow post-transplant regimen
 - Documented history of non-compliance
 - Inability to follow through with medication adherence or office follow-up
- ☐ Chronic illness with one year or less life expectancy
- ☐ Severe irreversible extra renal disease
- ☐ Limited, irreversible rehabilitation potential
- ☐ Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present
- ☐ No adequate social/family support

The requesting transplant recipient should be evaluated carefully and potentially treated if the following **relative contraindications** are present:

- Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation, this includes the following:
 - Smoking, documentation supporting free from smoking for 6 months
 - Active peptic ulcer disease
 - Active gastroesophageal reflux disease
 - Aggressive recurrent native kidney disease
- CVA with long term impairment that is not amenable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months
- Obesity with body mass index of >30 kg/m² may increase surgical risk

- 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
- 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.
- 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
- 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: [ONE] ⁵

- ☐ 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: [ONE]
 - 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.
 - 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.
 - 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.
- ☐ Candidates with sustained acute kidney injury and one of the following or a combination of both of the following, for the last 6 weeks:
 - Has been on dialysis at least once every 7 days, and/or
 - Has a measured or calculated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days
- ☐ Metabolic disease and a diagnosis of at least one of the following: [ONE]
 - Hyperoxaluria
 - Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I
 - Familial non-neuropathic systemic amyloidosis
 - Methylmalonic aciduria

CONTINUATION OF THERAPY

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

- ☐ If Molina Healthcare has authorized prior requests for transplantation, the following information is required for medical review: [ALL]
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;

- Kidney profile within the last 12 months;
- Cardiac update if history of cardiac disease within two years (≥ 50 years of age);
- Psychosocial evaluation or update within the last 12 months;
- 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.

☐ If authorized prior requests for transplantation were obtained from another insurer, the following information is required for medical review: [ALL]

- Authorization letter/documentation from previous insurer;
- Presence of no absolute contraindication as listed above;
- History and physical within the last 12 months;
- Kidney profile within the last 12 months;
- Cardiac update if history of cardiac disease within two years (≥ 50 years of age);
- Psychosocial evaluation or update within the last 12 months;
- 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.

SUMMARY OF MEDICAL EVIDENCE ^{5 7-29}

The published medical evidence and outcomes for Kidney transplantation in the United States consists of registry data obtained from transplant centers that perform kidney transplantation procedures and is available from the United Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants. ⁶

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

50547	Laparoscopic donor nephrectomy (including cold preservation), from living donor
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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	Description: [For dates of service on or after 10/01/2015]
N18.4	Chronic kidney disease Stage 4 severe
N18.5	Chronic kidney disease Stage 5
N18.6	End stage renal disease

REFERENCES

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33. IRO Peer Review:

- Policy reviewed by AMR practicing physician board certified in Surgical Critical Care, Surgery Vascular, Surgery General, Surgery, 10/19/17.
- Policy reviewed by AMR practicing physician Board certified in Internal Medicine, Nephrology, 1/23/20

REVIEW/REVISION HISTORY

2/28/08: New Policy

10/26/11: Policy reviewed, no changes

8/20/12: Pretransplant evaluation criteria added, adult and pediatric criteria changed, contraindications section changed, added criteria for simultaneous liver-kidney transplantation, professional guidelines updated.

1/14/13: Policy reviewed, no changes

11/20/14: This policy was reviewed and both the pretransplant and transplant criteria were updated.

12/16/15, 9/15/16, 9/19/17: Policy reviewed, no changes

12/13/17: The following revisions were added: The age for the pediatric criteria was changed to younger than 18 years of age (from 12). The professional guidelines and reference sections were updated.

9/13/18 & 9/18/19: Policy reviewed, no changes

4/23/20: Policy reviewed and clinical criteria was revised for a simultaneous liver and kidney transplant based on OPTN Policy 9.9. References and Guideline sections updated. Removed the CPT code 50380 from this policy.

6/9/21: Policy reviewed, no changes to criteria. Updated references.