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.

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.

RECOMMENDATION

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:

Criteria for transplant 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:
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

**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 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 older than 12 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
- All pre-transplant criteria are meet

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 < 200 cells/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 amendable 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-ureteric reflux, bladder extrophy, posterior urethral valve, vertebral/vascular anomalies, anal atresia, tracheoesophageal 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 supravesical 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: [ONE]

- End stage renal disease (ESRD) with cirrhosis and symptomatic portal hypertension or hepatic vein wedge pressure gradient ≥10 mmHg
- Hepatic failure and GFR ≤30 mL/min due to chronic kidney disease
- Acute kidney injury (AKI) or hepatorenal syndrome with serum creatinine ≥2 mg/dL (177 μmol/L) and dialysis ≥8 weeks
- Hepatic failure and chronic kidney disease with a kidney biopsy showing >30 percent glomerulosclerosis or >30 percent fibrosis

**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.

**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.

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<td>50320</td>
<td>Donor nephrectomy (including cold preservation); open, from living donor</td>
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<td>50340</td>
<td>Recipient nephrectomy (separate procedure)</td>
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<tr>
<td>50360</td>
<td>Renal allotransplantation, implantation of graft; without recipient nephrectomy</td>
</tr>
<tr>
<td>50365</td>
<td>Renal allotransplantation, implantation of graft; with recipient nephrectomy</td>
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<tr>
<td>50370</td>
<td>Removal of transplanted renal allograft</td>
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<tr>
<td>50380</td>
<td>Renal autotransplantation, reimplantation of kidney</td>
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<td>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</td>
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Rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

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**REFERENCES**


**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

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.

CMS does not have any NCD’s or LCD’s available for kidney transplantation in the adult or pediatric population.