Molina Clinical Policy
Renal Autotransplantation: Policy No. 361

Last Approval: 04/10/2024
Next Review Due By: April 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

Renal auto transplantation (RA) is a rare surgical procedure for the treatment of complex genitourinary conditions. The main objective in utilizing RA is to preserve renal parenchyma; however, it is generally reserved for severe conditions as a last option before nephrectomy. RA has been used in the treatment of different complex urologic diseases that include extensive ureteric injuries, complex nephrolithiasis, loin-pain hematuria syndrome, ureteral stricture disease, complex renovascular diseases (intrarenal aneurysms, renal artery stenosis, and arteriovenous malformations), tumors of the kidney and ureter, retroperitoneal fibrosis, and in other rare critical circumstances. Controversy remains over the use of RA in neoplastic disease. Renal auto transplantation may be a useful treatment in preventing kidney loss in highly selected circumstances and when conventional methods have failed (Han et al. 2023)

On rare occasions, RA is appropriate when kidneys with lesions of the renal artery or its branches are not amenable to in-situ reconstruction. In these circumstances, temporary removal of the kidney, ex-vivo preservation, microvascular repair (work-bench surgery), and RA may preserve kidney function. The decision to perform RA is typically made on a case-by-case basis and is often guided by the specifics of the patient as well as surgeon preference and expertise. RA should be performed by a qualified transplant surgeon in a center experienced in the procedure and involves removing the kidney from its original anatomic site, flushing the kidney with cold, anticoagulant electrolyte solution and revascularizing the kidney by connecting the renal and iliac vessels to a new site. The procedure may be performed by either an open, laparoscopic, or robotic approach (Bourgi et al. 2018; Decaestecker et al. 2018; Han et al. 2023).

COVERAGE POLICY

Renal auto transplantation **may be considered medically necessary** in selected patients on a case-by-case basis when **ALL** the following criteria have been met:

1. A Molina Medical Director has reviewed the case
2. A board-certified nephrologist and kidney transplant surgeon prescribed or is in consultation for the case/procedure
3. Procedure to be performed in an institution by a transplant surgeon with experience in renal auto transplantation
4. Documentation must be submitted for all medical and/or surgical treatment previously tried and failed
5. The procedure is in treatment for **ONE** of the following:
   a. Complex urologic diseases when repair of the kidney, ureter, renal artery, or its branches are not amenable to in-situ reconstruction, and **ONE** of the following is present:
      i. Abdominal aortic aneurysms that involve the origin of the renal arteries
      ii. Complex nephrolithiasis
      iii. Disease of the major vessels extends beyond the bifurcation of the main renal artery into the segmental branches

iv. Extensive atheromatous aortic disease when an operation on the aorta itself may prove hazardous
v. Extensive ureteric injuries
vi. Large aneurysms, arteriovenous fistulas, or malformations of the kidney
vii. Renovascular diseases (stenotic lesions of distal renal arteries, intrarenal aneurysms, and arteriovenous malformations)
viii. Retroperitoneal fibrosis
ix. Traumatic arterial injuries
x. Tumors of the kidney and ureter.

b. As a treatment of last resort for loin-pain hematuria syndrome that includes **ALL** the following:
i. History of chronic, progressive, and incapacitating loin/flank pain accompanied by hematuria with stable renal function
ii. History of chronic, progressive, and incapacitating loin/flank pain accompanied by hematuria with stable renal function
iii. Urological evaluation is negative for any underlying abnormality or dysfunction
iv. Nephrological and psychiatric causes for severe intractable flank pain and recurrent hematuria have been ruled out
v. Documentation of all medical and/or surgical treatment that has been previously tried and failed must be submitted for review.

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

Renal autotransplantation (RA) is a rare surgical procedure for the treatment of complex urologic conditions, and due to its rare nature, the evidence and peer reviewed literature is largely limited to case reports and relatively small- or moderately sized case series and retrospective studies.

Campsen et al. (2019) reported on the success rate of patients with LPHS post-transplant who received a percutaneous renal hilar blockade (RHB) and a multidisciplinary team (MDT) evaluation. A pain rating scale (0-10) was used with patients prior to RHB under CT guidance. For patients who reported a decrease in pain score by at least 50% were evaluated for RA. Pre-operative and 1-year post-operative quality-of-life surveys were administered to all patients. A total of 43 patients with LPHS were referred for RHB – of the 38 who received RHB, 31 had more than a 50% reduction in pain scores. Twenty-two patients who responded favorably proceeded to RA; 12 patients had at least one-year follow-up, and all had a significant decrease in pain (92% reported a $\geq$50% reduction in pain). Mean Beck Depression Inventory scores also improved at one-year follow-up. In conclusion, RHB with a MDT approach is appropriate for LPHS patients to achieve long-term success post-RA to improve chronic pain, depression, and quality of life.

Decaestecker et al. (2018) conducted a retrospective review of seven patients who underwent robot-assisted kidney autotransplantation (RAKAT) to describe the procedure's operative technique, perioperative complications, and early functional outcomes. Three males and four females underwent RAKAT for complex ureteral strictures (n=5), severe left renal vein nutcracker (n=1), and loin pain hematuria syndrome (n=1). Two patients underwent bench vascular reconstruction, and one patient underwent ex vivo flexible ureterorenoscopy. No patient needed open conversion. Median operative and console time was 370 and 255min, respectively, with median vascular and ureteral anastomosis time of 28 and 23min, respectively. Median warm, cold, and rewarming ischemia time was 2, 178, and 44min, respectively. One major postoperative complication occurred-wound dehiscence needing wound revision (grade 3b). Median hospital stay was 5 d. At 3 months, all patients were free of indwelling stents, pain, or hematuria. Median serum creatinine at 3 months was 0.80mg/dl and median calculated autotransplant glomerular filtration rate did not drop significantly. The authors concluded that RAKAT is feasible, safe, and results in good functioning of the autotransplant in selected patients with complex ureteral strictures, loin pain hematuria, or severe nutcracker syndrome.

Prasad et al. (2018) performed a single-arm, single-center study that included 12 patients with LPHS (ages 21 to 62; 11 females, 1 male) who underwent endovascular ablation of the renal nerves using the Vessix renal denervation system between July 2015 and November 2016. Using the McGill Pain Questionnaire (MPQ), 10 of 12 patients reported at least a 30% reduction in pain at 3 months; 11 of 12 patients reported at least a 30% reduction in pain at 6 months.

Improvements were also found in patient scores at six months post-procedure based on the Oswestry Disability Index (ODI), Geriatric Depression Scale (GDS), EuroQol-5D (EQ-5D), and the MOS 36-Item Short Form Survey (SF-36). Renal denervation should be considered for patients with LPHS due to significant improvement of patient pain, disability, quality of life, and mood. Further, the authors note that percutaneous catheter-based delivery of radiofrequency energy is an effective, quick, and safe treatment option.

Ruiz et al. (2017) conducted a retrospective analysis of fifteen patients who underwent RA at a single institution over the time period from January 1990 – December 2016. Indications for the procedure were vascular abnormalities in 8 cases and ureteral injury in 7. Nephrectomy was performed through laparoscopy in 2 cases (13.3%) and open in 13 (86.7%). Vascular grafts to re-perfuse the kidney were used in 8 patients, and ureteral reimplantation was performed in 11 cases. Mean hospital stay was 9.1 days (range 3-20). Seven patients (46.7%) developed postoperative complications: 6 minor (Clavien I-II) and 1 major (Clavien III). After a mean follow-up of 73.1 months (range 7-312), 80% of the patients have a functioning graft. Graft survival is variable, and complications are frequent, but usually minor. The authors concluded the RA is an effective treatment for complex ureteral lesions and kidney vascular abnormalities, with satisfactory results in the long term. Surgical complications are frequent, but usually minor. As a challenging surgery, experienced kidney transplant surgeons should perform it.

Cowan et al. (2015) conducted a retrospective analysis of 51 patients who underwent RA at two institutions from 1986 – 2013. Among the 51 patients, a total of 54 renal autotransplants were performed. The most common indications were loin pain hematuria syndrome/chronic kidney pain in 31.5% of cases, ureteral stricture in 20.4% and vascular anomalies in 18.5%. Autotransplantation of a solitary kidney was performed in 5 patients. Laparoscopic nephrectomy was performed in 23.5% of cases. Median operative time was 402 minutes and median length of stay was 6 days. No significant difference was found between preoperative and postoperative plasma creatinine ($p = 0.74$). Early, high-grade complications (grade IIIa or greater) developed in 14.8% of patients and 12.9% experienced late complications of any grade, with two graft losses. Overall, complication rates compared favorably with those of other major urological operations and cold ischemia time was the only predictor of postoperative complications.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

Code	Description
50380	Renal auto transplantation, reimplantation of kidney

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

04/10/2024	Policy reviewed. No changes to coverage criteria. IRO Peer Reviewed on March 21, 2024, by a practicing physician board certified in Internal Medicine and Nephrology.
04/13/2023	Policy reviewed. No changes to coverage criteria.
04/13/2022	Policy reviewed. No changes to coverage criteria.
04/05/2021	Policy reviewed. No changes to coverage criteria.
04/23/2020	New policy. IRO Peer Review on February 25, 2020, by a practicing physician board certified in General Surgery and Transplant Surgery.

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