Molina Clinical Policy
Renal Autotransplantation: Policy No. 361

Last Approval: 4/13/2023
Next Review Due By: April 2024

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 urologic conditions. It was first reported by J. D. Hardy in 1963 when he repaired a high ureteric injury following aortic surgery by reimplanting the repaired organ into the ipsilateral iliac fossa. The main reason for the use of RA is to preserve renal parenchyma, is generally reserved for severe conditions and is often the 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, renovascular diseases (stenotic lesions of distal renal arteries, intrarenal aneurysms, and arteriovenous malformations), tumors of the kidney and ureter, and retroperitoneal fibrosis, and in other rare and unusual critical circumstances. Controversy remains over the use of RA in neoplastic disease. Renal auto transplantation may be a useful treatment of last resort in preventing kidney loss in highly selected circumstances and when conventional methods have failed. On rare occasions, 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 permit preserved 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 both the open and laparoscopic approach (Bourgi et al., 2018; Azhar et al., 2015).

Loin pain hematuria syndrome (LPHS) describes a rare condition with a constellation of symptoms that is estimated to have a prevalence of approximately 0.012% and primarily occurs in women. The most significant symptom that patients experience is severe flank (loin) pain that may be unilateral or bilateral and radiates to the abdomen, medial thigh, or groin. Pain may be intermittent or constant and can be exacerbated by common daily activities such as exercise or riding in a car. As a result of this debilitating pain, patients often require large quantities of narcotics for pain control. Additionally, patients may experience micro- or macroscopic hematuria. LPHS has been differentiated as type 1 or type 2 LPHS. Type 1 LPHS can be attributed to identifiable causes including nutcracker syndrome, nephrolithiasis, polycystic kidney disease, recurrent renal papillary necrosis with ureteral obstruction, renal thromboembolism, or renal artery dissection. Cases in which diagnostic work-up does not reveal an etiology have been categorized as type 2 LPHS. As a result of the fact that pathology cannot be established in a subset of patients with LPHS, these patients are often labeled as having a somatoform pain disorder or drug-seeking behavior. At the current time, there is no disease-specific treatment or cure for LPHS since the source of the disease is not understood. Unless the cause of glomerular disease is treatable, the treatment of primary and secondary LPHS focuses on pain management. The work-up and tests to rule out other possible causes of loin pain and blood in the urine may include (Hebert et al., 2022; Steele, 2021; Beth et al., 2018; NIH, 2018):

- Urine culture to rule out infection
- Urinalysis to check for glomerular disease
- Endoscopy of urethra and bladder (cystoscopy) and/or CT scan to rule out kidney stones, tumors, and cysts
- Angiography or CT angiography) to rule out arteriovenous malformations
- Upper urinary tract endoscopy (flexible ureteroscopy) to rule out ureteral problems
- Blood tests to rule out bleeding disorders
- Kidney biopsy to rule out secondary LPHS if there are any signs of glomerular disease

COVERAGE POLICY

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

1. Molina Medical Director review is required; **AND**
2. Prescribed by, or in consultation with, a board-certified nephrologist and kidney transplant surgeon; **AND**
3. Performed in an institution by a transplant surgeon with experience in renal auto transplantation; **AND**
4. Documentation must be submitted of all medical and/or surgical treatment previously tried and failed; **AND**

AND

5. For the treatment of complex urologic diseases when repair of the kidney, ureter, renal artery, or its branches are not amenable to in-situ reconstruction, **ONE** of the following must be present:
   - Abdominal aortic aneurysms that involve the origin of the renal arteries; **OR**
   - Complex nephrolithiasis; **OR**
   - Disease of the major vessels extends beyond the bifurcation of the main renal artery into the segmental branches; **OR**
   - Extensive atheromatous aortic disease when an operation on the aorta itself may prove hazardous; **OR**
   - Extensive ureteric injuries; **OR**
   - Large aneurysms, arteriovenous fistulas, or malformations of the kidney; **OR**
   - Renovascular diseases (stenotic lesions of distal renal arteries, intrarenal aneurysms, and arteriovenous malformations); **OR**
   - Retroperitoneal fibrosis; **OR**
   - Traumatic arterial injuries; **OR**
   - Tumors of the kidney and ureter.

OR

6. As a treatment of last resort for loin-pain hematuria syndrome that includes **ALL** the following:
   - History of chronic, progressive, and incapacitating loin/flank pain accompanied by hematuria with stable renal function; **AND**
   - Urological evaluation is negative for any underlying abnormality or dysfunction; **AND**
   - Nephrological and psychiatric causes for severe intractable flank pain and recurrent hematuria have been ruled out; **AND**
   - 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

The evidence and peer reviewed literature for RA are largely limited to case reports and relatively small- or moderately sized case series and retrospective studies. No meta-analysis, randomized controlled trials (RCTs), comparative studies, or professional society guidelines are available. Renal autotransplant is a rare surgical procedure for the treatment of complex urologic conditions. Because it is a rare procedure for complex conditions, RCTs are not expected to be completed and published. Moderate sized case series and retrospective studies have shown RA to be effective with positive long-term outcomes. In select cases, RA may be of significant utility for kidney salvage.

At the current time there are no RCTs in the peer reviewed literature evaluating the treatment of LPHS. Renal autotransplant has been used in LPHS patients with chronic, severe pain that has been unresponsive to nonsurgical therapies. However, this approach is now regarded as a treatment of last resort. Moderate sized case series and retrospective studies have shown RA to be effective with positive long-term outcomes (reduction of pain) in select patients with LPHS.

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.

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.

Bath et al. (2018) analyzed developed the UW-LPHS test as a diagnostic tool to identify patients with LPHS who would benefit from RA. Bupivacaine is instilled into the ureter on the affected side and left to dwell. Patients who experience pain relief after this diagnostic test will benefit from RA. Here we describe this novel diagnostic test and initial success rates following RA. While conservative management and surgical intervention have mixed results, multiple case series report high success rates with RA. The authors note a series of 48 patients who under RA – 70% had sustained pain relief however, smaller series have reported pain recurrence up to 73%. The authors noted that current results demonstrate that the UW-LPHS is a simple, reliable method to identify patients. Sollinger et al. (2018) conducted a pilot study to determine if the UW-LPHS test definitively localizes pain from patients' LPHS to the ureter. The authors also sought to understand whether a positive UW-LPHS test predicts a successful outcome after RA. All 6 study patients reported complete pain relief at a mean follow-up of 9.2 months after RA. All patients successfully weaned from opioids and returned to a normal lifestyle.

CODING & BILLING INFORMATION

CPT Code

CPT	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

4/13/2023	Policy reviewed, no changes, included note re: cannabis use in Coverage Policy section.
4/13/2022	Policy reviewed, no changes, updated references.
4/5/2021	Policy reviewed, no changes, updated references.
4/23/2020	New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed March 13, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.

Peer Reviewed Publications

1. Bath NM, Williams DH, et al. Commentary: Loin pain hematuria syndrome. J Rare Dis Res Treat. 2018;3(4):1-3. doi: 10.29245/2572-9411/2018/4.1169. PMID: 30984919. PMCID: PMC6457464.
2. Bourgi A, Aoun R, et al. Experience with renal autotransplantation: Typical and atypical indications. Adv Urol. 2018 Mar 26;2018:3404587. doi: 10.1155/2018/3404587.
3. Campsen J, Bassett MR, O'Hara R, et al. Renal hilar block predicts long-term success of renal auto-transplantation for loin pain hematuria syndrome. Int Urol Nephrol. 2019;51(6):927-930. doi: 10.1007/s11255-019-02143-z. PMID: 30977018. PMCID: PMC6543029.
4. de Jager RL, Casteleijn NF, de Beus E, et al. Catheter-based renal denervation as therapy for chronic severe kidney-related pain. Nephrol Dial Transplant. 2018;33(4):614-619. doi: 10.1093/ndt/gfx086. PMID: 28645206.
5. Prasad B, Giebel S, Garcia F, Goyal K, Shrivastava P, Berry W. Successful use of renal denervation in patients with loin pain hematuria syndrome: The Regina Loin Pain Hematuria Syndrome Study. Kidney Int Rep. 2018 Feb 2;3(3):638-644. Doi: 10.1016/j.ekir.2018.01.006. PMID: 29854971. PMCID: PMC5976818.
6. Sollinger HW, Al-Qaoud T, Bath N, Redfield RR. The UW-LPHS test: A new test to predict the outcome of renal autotransplant for loin pain hematuria syndrome. Exp Clin Transplant. 2018;16(6):651-655. doi: 10.6002/ect.2018.0236. PMID: 30251941. PMCID: PMC6478157.

National and Specialty Organization

1. National Institutes of Health (NIH) Genetic and Rare Disease Information Center (GARD). Loin pain hematuria syndrome. Accessed March 13, 2023. https://rarediseases.info.nih.gov/diseases/6920/loin-pain-hematuria-syndrome.

Other Authoritative Publications

1. AMR Peer Review. Policy reviewed on February 25, 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician(s) in the areas of General Surgery and Transplant Surgery.
2. Hebert LA, Benedetti C, et al. Loin pain-hematuria syndrome. Updated April 8, 2022. Accessed March 13, 2023. http://www.uptodate.com.
3. Steele G. Surgical repair of an iatrogenic ureteral injury. Updated May 26, 2021. Accessed March 13, 2023. http://www.uptodate.com.