

Molina Clinical Policy

Renal Autotransplantation: Policy No. 361

Last Approval: 4/13/2022
Next Review Due By: April 2023



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.¹ References included were accurate at the time of policy approval and publication.

OVERVIEW

Renal autotransplantation (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 autotransplant in neoplastic disease. Renal autotransplant 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 autotransplantation 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 or laparoscopic approach (Azhar et al., 2015; Bourgi et al., 2018).

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 loin pain hematuria syndrome (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 (Beth et al., 2018; NIH, 2018; Hebert et al., 2021; Steele, 2021):

- 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

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- 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 Autotransplantation **may be considered medically necessary** in selected patients on a case-by-case basis after medical director review when **ALL** of 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 autotransplantation; **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** of 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 renal autotransplantation (RA) are largely limited to case reports and relatively small- or moderately sized case series and retrospective studies. There are no meta-analysis, randomized controlled trials (RCTs), comparative studies or professional society guidelines. Renal autotransplantation is a rare

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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 Loin Pain Hematuria Syndrome (LPHS). Kidney autotransplantation 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.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Code

| CPT | Description |
|-------|---|
| 50380 | Renal autotransplantation, reimplantation of kidney |

HCPCS Codes – N/A

ICD-10 Codes – N/A

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

4/13/2022 Policy reviewed, no changes, updated references.
4/5/2021 Policy reviewed, no changes, updated references.
4/23/2020 New policy.

REFERENCES

Government Agency

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from [CMS](https://www.cms.gov). Accessed February 28, 2022.

Peer Reviewed Publications

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National and Specialty Organizations

- National Institutes of Health (NIH) Genetic and Rare Disease Information Center (GARD). Loin pain hematuria syndrome. Available from [NICE](#). Accessed February 28, 2022.

Other Evidence Based Reviews and Publications

- 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.
- Hebert LA, Benedetti C, et al. Loin pain-hematuria syndrome. Available from [UpToDate](#). Updated September 21, 2021. Accessed February 28, 2022. Registration and login required.
- Steele G. Surgical repair of an iatrogenic ureteral injury. Available from [UpToDate](#). Updated May 26, 2021. Accessed February 28, 2022. Registration and login required.

APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.