

Subject: Renal Autotransplantation		Original Effective Date: 4/23/20
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Contents

DISCLAIMER	1
Description of Procedure/Service/Pharmaceutical.....	1
Recommendation Clinical Criteria.....	2
Summary of Medical Evidence.....	3
Coding Information.....	3
References.....	4
REVISION/REVIEW HISTORY	5

DISCLAIMER

This Molina clinical policy 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 document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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.³⁻⁴

Loin Pain-Hematuria Syndrome²²⁻²⁴

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:

- Urine culture to rule out infection
- Urinalysis to check for glomerular disease
- Endoscopy of the 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

RECOMMENDATION CLINICAL CRITERIA²⁻²⁰

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: [ALL]

- ☐ Molina Medical Director review is required; and
- ☐ Prescribed by, or in consultation with, a board-certified nephrologist and kidney transplant surgeon; and
- ☐ Performed in an institution by a transplant surgeon with experience in renal autotransplantation; and
- ☐ Documentation must be submitted of all medical and/or surgical treatment that has been previously tried and failed; and
- ☐ 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]
 - Abdominal aortic aneurysms that involve the origin of the renal arteries;
 - Complex nephrolithiasis;

- Disease of the major vessels extends beyond the bifurcation of the main renal artery into the segmental branches;
 - Extensive atheromatous aortic disease when an operation on the aorta itself may prove hazardous;
 - Extensive ureteric injuries,
 - Large aneurysms, arteriovenous fistulas, or malformations of the kidney;
 - Renovascular diseases (stenotic lesions of distal renal arteries, intrarenal aneurysms, and arteriovenous malformations),
 - Retroperitoneal fibrosis
 - Traumatic arterial injuries
 - Tumors of the kidney and ureter; or
- ☐ As a treatment of last resort for loin-pain hematuria syndrome that includes all of the following: [ALL]
- 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

SUMMARY OF MEDICAL EVIDENCE ²⁻²⁰

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, RCT's, comparative studies or professional society guidelines. Renal autotransplantation is a rare surgical procedure for the treatment of complex urologic conditions. Because it is a rare procedure for complex conditions, RCT's 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 RCT's 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.

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
50380	Renal autotransplantation, reimplantation of kidney

HCPCS	Description
	N/A

ICD-10	Description:
	Any/All

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

Peer Reviewed Publications

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3. Azhar B et al. Indications for Renal Autotransplant: An Overview. *Experimental and Clinical Transplantation* (2015) 2: 109-114
4. Bourgi A et al. Experience with Renal Autotransplantation: Typical and Atypical Indications. *Advances in Urology*. 2018. Accessed at: <https://www.hindawi.com/journals/au/2018/3404587/>
5. Campsen J, Bassett MR, O'Hara R, et al. Renal hilar block predicts long-term success of renal autotransplantation for loin pain hematuria syndrome. *Int Urol Nephrol*. 2019;51(6):927-930.
6. Chin JL et al. Renal autotransplantation for the loin pain-hematuria syndrome: long-term follow up of 26 cases. *J Urol*. 1998 Oct;160(4):1232-5; discussion 1235-6.
7. Cowan Ng et al. Renal Autotransplantation: 27-Year Experience at 2 Institutions. *J Urol*. 2015 Nov;194(5):1357-61. doi: 10.1016/j.juro.2015.05.088. Epub 2015 Jun 6.
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16. Shell AG et al. Evaluation of the loin pain/hematuria syndrome treated by renal autotransplantation or radical renal neurectomy.
17. 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.

18. Spitz A. Autotransplantation as an effective therapy for the loin pain-hematuria syndrome: case reports and a review of the literature. J Urol. 1997 May;157(5):1554-9.
19. Taba Taba Vakili S, Alam T, Sollinger H. Loin pain hematuria syndrome. Am J Kidney Dis. 2014 Sep;64(3):460-72. Epub 2014 Apr 13.
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Professional Society Guidelines

21. N/A

Other Resources

22. Bath NM, Williams DH et al. Commentary: Loin Pain Hematuria Syndrome. Journal of Rare Diseases Research & Treatment. Nov, 2018.
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REVISION/REVIEW HISTORY

4/23/20: New Policy

4/5/21: Policy reviewed, no changes to criteria, references updated.