Molina Clinical Policy
Steerable Ureteroscopic Renal Evacuation (SURE): MEDICARE
Policy No. 477b

Last Approval: 12/17/2025
Next Review Due By: December 2026

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

Nephrolithiasis, kidney stones, is a common medical problem among adults. The stones may form from different substances (e.g., uric acid, struvite, cystine) but are often caused by calcium build up. Classic symptoms are renal colic, hematuria, and pain dependent on stone location. Kidney stones are typically diagnosed through laboratory tests, such as renal labs and urinalysis, and diagnostic imaging. Most stones pass on their own; though, as the size of the stone(s) increases, so does the probability of needing medical intervention to aid in their evacuation. Conservative treatment involves a four-week trial of medication to facilitate the passage of the stones. An urgent urology consult is warranted in the event of large stones (> 10mm), a concurrent urinary tract infection, intense pain affecting daily life, acute kidney injury, anuria, or for patients who fail conservative therapy (Curhan et al. 2025).

Approximately 10 – 20% of nephrolithiasis cases require surgical intervention to evacuate the kidney stones (Preminger 2025). Surgical options include basket ureteroscopy, shock wave lithotripsy, or percutaneous nephrolithotomy. Ureteroscopy and shock wave lithotripsy are typically first line treatments but have higher rates of residual stone debris than percutaneous nephrolithotomy, which is mainly reserved for large or complex stones due to its higher complication rates (Preminger 2025). Ureteroscopy and shock wave lithotripsy are both minimally invasive techniques, while percutaneous nephrolithotomy involves an invasive approach with surgical incisions.

Steerable Ureteroscopic Renal Evacuation (SURE) is a procedure that utilizes the CVAC aspiration system by Calyxo Inc. This novel procedure combines the minimally invasive nature of a ureteroscopy with a suction system to increase the percentage of stone fragment evacuation during lithotripsy (Calyxo 2025). The CVAC system inserts a flexible rod that allows for the deliverance of laser lithotripsy, irrigation, suction, and stone collection simultaneously. The intention is that with continuous irrigation and suction, the system will be able to evacuate almost all stone fragments and dust, thus preventing residual complications or the need for subsequent procedures.

Regulatory Status

The CVAC Aspiration System and CVAC Image Processor (Calyxo Inc., Pleasanton CA) was granted FDA approval on February 2, 2024. It is registered in the 510(k) Premarket Database under the product codes FED and FGB (Endoscopic Access Overtube, Gastroenterology-Urology), and 510(k) number K233472. It is currently the only FDA approved device for the SURE procedure.

COVERAGE POLICY

Steerable Ureteroscopic Renal Evacuation (SURE) procedure is considered **experimental, investigational, and unproven** for the removal of kidney stones and accompanying debris due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE

While the evidence is promising for the Steerable Ureteroscopic Renal Evacuation (SURE) procedure, there is a lack of large scale randomized controlled trials demonstrating superior outcomes over current minimally invasive treatments. Additionally, the available randomized controlled trials have a short term follow up, leading to a lack of evidence of the long-term safety profile for this procedure.

Randomized Controlled Trials

Matlaga et al. (2025) conducted the ASPIRE study, a prospective, randomized, controlled, noninferiority study to evaluate the safety and efficacy of the SURE procedure versus standard ureteroscopy. Inclusion criteria were adult patients with at least one kidney stone between 7 – 20mm. The primary endpoint was to demonstrate a noninferior stone free rate, defined as percentage of subjects with zero residual fragments at 30 days post procedure, compared to basket ureteroscopy. A total of 101 participants were randomized, 46 to the SURE group and 55 to the standard basket ureteroscopy (URS) group. The SURE procedure demonstrated significant superiority in stone clearance and residual stone volume at 30 days post procedure, though the was no significant difference between residual fragment rates between the two groups. With these results, the primary outcome was achieved. Additionally, the researchers found that stone clearance was not dependent on baseline stone burden, nor was there evidence of a relationship between residual stone volume and baseline stone volume with the SURE procedure, where a higher baseline stone burden revealed a higher rate of residual stone volume and less stone clearance in the URS group. There were no differences in adverse events between both groups, most of which were mild and resolved spontaneously, nor did any patient require retreatment during the 30 day follow up.

Sur et al. (2022) conducted a feasibility study of the SURE procedure compared to standard basket extraction. Nineteen patients were randomized with 11 in the SURE group and 8 in the basket group. The primary endpoint was a safety demonstration of the SURE procedure, which was achieved when there were no serious adverse events in either group. Both groups had one adverse event, a self-limiting ileus in the SURE group and a urinary tract infection in the basket group. Additionally, there were no differences in fluoroscopy or procedure time between the groups. The feasibility endpoint was achieved, as the SURE procedure was successful in every participant. Stone volume and total stone volume removed were significantly greater with the SURE procedure compared with basket extraction (202 mm^3 *vs* 91 mm^3, $p < 0.01$ and 84% *vs* 56%, $p = 0.022$). Based on CT image findings, the SURE procedure had a 100% stone free rate compared to 75% for basket group ($p = 0.20$), although this difference was not statistically significant.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Stern at al. (2023) conducted a feasibility study of the SURE procedure in patients with large stone burdens. A total of 43 adult patients with a stone burden $\geq$ 10mm underwent the SURE procedure. The average stone clearance was 96.1% and 8 patients (33.3%) had no residual fragments. Stone clearance based on baseline stone burden varied and were as follows: 97.9% stone clearance was achieved for baseline total stone burden 10–20 mm, 98.9% for baseline stone burdens 20–30 mm, and 93.8% for baseline stone burden >30 mm. Six of 43 patients (14.0%) had a secondary surgical intervention, including two planned secondary ureteroscopies, and there were no serious adverse events. The results demonstrated that the SURE procedure was effective at removing stone fragments in patients with large baseline stone burdens.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if necessary, with use of steerable ureteral catheter or suction-integrated ureteroscope

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

APPROVAL HISTORY

12/17/2025 New policy. IRO Peer Reviewed on November 24, 2025, by a practicing physician board certified in Urology.

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