
Medical Policy



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. When Centers for Medicare and Medicaid (CMS) coverage rules are not fully developed, this medical policy may be used by BCBSM or BCN Medicare Advantage plans 42 CFR § 422.101 (b)(6). Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 11/1/25**
(See policy history boxes for previous effective dates)

Title: Steerable Ureteroscopic Renal Evacuation (SURE Procedure) with Vacuum-Assisted Stone Removal Systems for Kidney Stone Management

Description

Steerable Ureteroscopic Renal Evacuation (SURE Procedure) utilizes steerable catheters that can access individual renal calyces while simultaneously providing irrigation and vacuum suction to remove fragmented stone material. Vacuum-assisted stone removal systems are endoscopic devices that combine laser lithotripsy with continuous vacuum aspiration to extract kidney stone fragments during ureteroscopy. The technology is designed to enhance stone clearance rates compared to conventional ureteroscopy by actively removing debris rather than relying on passive stone passage or manual basketing techniques.

Medical Policy Statement

Steerable Ureteroscopic Renal Evacuation (SURE Procedure) with vacuum assisted stone removal systems for kidney stone management is **established** when specific criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions

Stone Characteristics:

- Renal stones ≥ 7 mm in maximum diameter, **OR**

- Multiple renal stones with total stone burden $\geq 100\text{mm}^3$, **OR**
- Stones located in calyceal locations difficult to access with conventional ureteroscopy

Exclusions

Absolute Contraindications:

- Active, untreated urinary tract infection
- Opaque or turbid fluid in the collecting system
- Uncorrected coagulopathy or bleeding disorders

Clinical Circumstances:

- Stones amenable to medical dissolution therapy
- Small stones (< 5mm) likely to pass spontaneously
- Individuals with severe comorbidities precluding safe anesthesia
- Anatomical abnormalities preventing safe ureteroscopic access

Alternative Treatment More Appropriate:

- Large staghorn calculi requiring Percutaneous Nephrolithotomy
- Ureteral stones better managed with conventional Ureteroscopy
- Stones requiring open surgical intervention

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

52352 52353 C9761

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Background

Nephrolithiasis affects approximately 10% of the population and represents a significant clinical burden with high recurrence rates. The management of kidney stones follows a stepwise approach beginning with conservative measures including increased fluid intake, pain management with non-steroidal anti-inflammatory drugs, and medical expulsive therapy for stones expected to pass spontaneously.

For stones that require intervention, treatment selection depends on stone size, location, composition, and patient factors. Current surgical options include extracorporeal shock wave lithotripsy (ESWL), ureteroscopy with laser lithotripsy (URS), and percutaneous

nephrolithotomy (PCNL). ESWL is typically reserved for stones less than 2 cm in diameter and is most effective for stones in the renal pelvis and upper ureter. However, ESWL may be ineffective for very dense, hard stones and requires patients to pass fragments naturally, potentially causing additional pain or obstruction.

Ureteroscopy involves passage of a small telescope through the urethra, bladder, and ureter to directly visualize and treat stones. During URS, holmium laser lithotripsy breaks stones into fragments that are then removed with baskets or left to pass spontaneously. While effective, conventional URS may require multiple procedures for complete stone clearance, particularly for larger stone burdens or stones in difficult anatomical locations.

PCNL involves creating a percutaneous tract through the skin to access the kidney directly and is typically reserved for large, complex stones that cannot be effectively treated with less invasive methods. However, PCNL carries higher morbidity due to its invasive nature.

The limitations of current treatments include incomplete stone clearance leading to residual fragments, multiple procedures for large stone burdens, and potential complications from retained stone material. Vacuum-assisted stone removal systems were developed to address these limitations by providing continuous fragment removal during laser lithotripsy, potentially achieving more complete stone clearance in fewer procedures.

Summary of Evidence

The clinical evidence for vacuum-assisted stone removal systems demonstrates consistent and significant advantages across multiple parameters of kidney stone management. All studies consistently demonstrated superior stone-free rates with vacuum-assisted systems compared to conventional approaches, with immediate stone-free rates ranging from 78.6% to 85.3% versus 50.5% to 70.3% for conventional methods. The ASPIRE trial's Level 1 evidence confirmed superior stone clearance regardless of baseline stone volume, while vacuum-assisted systems consistently reduced operative times by up to 20% and decreased auxiliary procedure requirements from 17.2% to 5.9%. However, Sun et al. (2023) found significantly lower early stone-free rates with vacuum-assisted ureteral access sheath (73.2% vs. 86.2%; $p = 0.034$) for infectious ureteral stones, and Zeid et al. (2023) demonstrated that small-tract approaches similar to vacuum-assisted platforms resulted in longer operative times and increased procedural complexity for larger stones. While the supportive evidence remains compelling, these conflicting studies indicate that the durability of vacuum-assisted systems' superiority will continue to be questioned as broader clinical implementation reveals context-specific limitations. The technology demonstrates comparable or improved safety profiles across supportive studies, with the double-sheath system significantly reducing fever rates requiring antibiotics and high-risk patient studies showing reduced infectious complications, though these benefits may be selectively applicable based on stone characteristics and clinical context. The evidence for Steerable Ureteroscopic renal evacuation (SURE Procedure) with Vacuum-assisted Stone removal systems for kidney stone management is sufficient.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific

outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

This comparative study published in *Scientific Reports* evaluated a novel double-sheath negative-pressure minimally invasive percutaneous nephrolithotomy (D-mPCNL) versus conventional minimally invasive PCNL (C-mPCNL) for large kidney stones (Tuoheti et al., 2023). The study included 132 patients with large kidney stones (>20mm), with 68 patients receiving D-mPCNL and 64 receiving C-mPCNL. The D-mPCNL system utilized a unique double-sheath design consisting of a 20F Y-shaped outer sheath connected to perfusion flow and a 16F Y-shaped inner sheath connected to vacuum suction. The gap between sheaths served as the perfusion inflow channel, while the inner sheath lumen functioned as the outflow channel. Lithotripsy was performed using a 550- μ m holmium-YAG laser with energy levels of 1.2–2.0 J, frequency of 30–40 Hz, perfusion flow rate of 50–80 ml/min, and vacuum suction pressure of 150–250 mmHg. The conventional group used standard 20F peel-away sheaths with perfusion rates of 90–120 ml/min.

The D-mPCNL group demonstrated statistically significant improvements across multiple parameters (Tuoheti et al., 2023). Operative time was significantly reduced (41.97 ± 8.24 min vs. 52.30 ± 13.72 min; $P < 0.000$), representing a 20% reduction in surgical duration. The primary stone-free rate was notably higher in the vacuum-assisted group (85.3% vs. 70.3%; $P = 0.038$). Postoperative complications were substantially reduced, with fever rates requiring additional antibiotics significantly lower (2.9% vs. 14.1%; $P = 0.021$). The need for auxiliary procedures was also reduced (5.9% vs. 17.2%; $P = 0.041$), indicating more complete stone clearance in a single procedure. The vacuum system's ability to maintain continuous aspiration provided clearer visualization and more efficient fragment removal without increasing renal pelvic pressure.

This propensity-matched study published in *World Journal of Urology* compared vacuum-assisted dedusting lithotripsy (VADL) with conventional flexible ureteroscopic lithotripsy for kidney and proximal ureteral stones less than 3 cm in size (Huang et al., 2023). Following 1:1 propensity score matching, 103 well-matched patients were identified in each group. The VADL technique employed a flexible vacuum-assisted ureteral access sheath that enabled continuous aspiration of stone dust and fragments during lithotripsy. The system was designed to prevent stone fragment migration and improve visualization by removing debris in real-time. Patients underwent flexible ureteroscopic lithotripsy with holmium laser fragmentation, with the vacuum system actively removing stone particles during the procedure. Stone-free rates were assessed both immediately post-operatively and at follow-up.

The VADL group achieved significantly superior stone-free rates compared to conventional ureteroscopy (Huang et al., 2023). The immediate stone-free rate was markedly higher (78.6% vs. 50.5%), demonstrating the vacuum system's effectiveness in removing stone fragments during the initial procedure. Follow-up stone-free rates remained significantly better in the VADL group, indicating sustained clinical benefit. The study found no cases of septic shock or death in either group, confirming the safety profile of the vacuum-assisted approach. Stratified analyses based on stone size and location consistently showed advantages for the VADL

technique, suggesting broad applicability across different stone characteristics within the size range studied.

The multicenter ASPIRE trial was a prospective, randomized controlled study comparing the safety and efficacy of Steerable Ureteroscopic Renal Evacuation (SURE) using the CVAC (Continuous Vacuum-Assisted Collection) System versus standard ureteroscopy with basketing in 123 patients (BioSpace, 2024). This Level 1 evidence study represents landmark data in vacuum-assisted stone removal technology. The CVAC System is an all-in-one vacuum-assisted stone removal platform that combines steerable aspiration catheters with continuous irrigation and suction capabilities. Patients were randomized to receive either SURE with CVAC or standard ureteroscopy with laser lithotripsy and basket extraction. The primary endpoints included stone-free rates and stone volume clearance, while secondary endpoints assessed safety parameters and healthcare utilization. One-year follow-up data evaluated long-term outcomes including emergency department visits and repeat procedures.

The ASPIRE trial demonstrated superior stone clearance with the CVAC system regardless of baseline stone volume compared to standard ureteroscopy (BioSpace, 2024). The SURE procedure achieved significantly better stone volume removal, addressing a critical limitation of conventional basketing techniques that often leave residual fragments. Safety profiles were comparable between groups, with the vacuum-assisted approach showing no increased risk of complications. Long-term follow-up data revealed reduced healthcare consumption in the CVAC group, including fewer emergency department visits and decreased need for repeat interventions. The study's Level 1 evidence status provides the highest quality clinical support for vacuum-assisted stone removal technology in urological practice.

This multi-institutional retrospective study evaluated the safety and effectiveness of the CVAC Aspiration System for treating large stone burdens, including high-risk patients (Ghani et al., 2023). The study specifically focused on patients with substantial stone loads who would traditionally require more invasive procedures like percutaneous nephrolithotomy (PCNL). The study employed the CVAC system's steerable aspiration technology for treating large renal stones across multiple centers. Patients included those with significant comorbidities and complex stone anatomies. The vacuum-assisted approach utilized continuous aspiration during laser lithotripsy to remove stone fragments in real-time, potentially eliminating the need for more invasive surgical approaches. Outcome measures included stone-free rates, complication rates, and the need for secondary procedures or PCNL conversion.

The CVAC system demonstrated safety and effectiveness even in high-risk patients with large stone burdens (Ghani et al., 2023). The study found that vacuum-assisted stone removal could potentially decrease the need for PCNL or secondary procedures, offering a less invasive alternative for patients who would otherwise require more aggressive surgical intervention. The technology's ability to handle large volumes of stone material while maintaining safety profiles comparable to conventional approaches represents a significant advancement in endoscopic stone management. The multi-institutional nature of the study provides broader validation of the technology's reproducibility across different surgical teams and healthcare settings.

This recent retrospective comparative study specifically examined VADL in high-risk patients with positive preoperative urine cultures undergoing ureteroscopic lithotripsy (Huang et al., 2025). The study addressed a particularly challenging patient population where infection risk is elevated and stone clearance is critical for preventing complications. The study compared

VADL with conventional flexible ureteroscopic lithotripsy in patients with upper urinary tract stones and documented positive preoperative urine cultures. The vacuum-assisted approach was hypothesized to reduce bacterial load and stone debris that could contribute to postoperative infectious complications. Patients underwent standard preoperative evaluation including urine culture and sensitivity testing, with appropriate antibiotic prophylaxis administered according to culture results.

VADL significantly reduced postoperative infectious complications in this high-risk population, demonstrating particular value in patients with preexisting bacteriuria (Huang et al., 2025). The enhanced stone-free rates achieved with vacuum assistance were especially important in infected cases, where incomplete stone clearance can lead to persistent infection and serious complications. The study's findings suggest that vacuum-assisted technology may be particularly beneficial in challenging clinical scenarios where both stone clearance and infection control are critical objectives. The reduction in infectious complications represents both improved patient safety and potentially significant healthcare cost savings through reduced hospital readmissions and antibiotic usage.

This comparative study evaluated a novel vacuum suction ureteroscopic lithotripsy system specifically for upper ureteral calculi, comparing outcomes with both rigid and flexible conventional approaches (Li et al., 2021). The study focused on the technical challenges specific to ureteral stone management, where stone migration and visualization can be particularly problematic. The vacuum suction system was designed to address the specific challenges of ureteral stone treatment, including prevention of stone migration during fragmentation and improved debris clearance from the ureter's confined space. The study compared outcomes between the novel vacuum approach and conventional rigid and flexible ureteroscopic techniques. Particular attention was paid to stone-free rates in complicated cases where conventional approaches had historically shown limitations.

The novel vacuum suction ureteroscopic lithotripsy significantly improved stone-free rates, especially in complicated cases, compared to both rigid and flexible conventional approaches (Li et al., 2021). Importantly, the improved outcomes were achieved without increases in complication rates or treatment costs, addressing key concerns about new technology adoption. The vacuum system's ability to maintain stone fragments in position during lithotripsy and efficiently clear debris from the ureter resulted in more complete stone clearance and reduced need for repeat procedures. The study's demonstration of particular benefit in complicated cases suggests that vacuum-assisted technology may be most valuable in challenging clinical scenarios where conventional approaches have limited success.

In a prospective randomized controlled trial, the effectiveness of a vacuum-assisted ureteral access sheath (V-UAS) was evaluated in comparison to standard minimally invasive percutaneous nephrolithotomy (MPCNL) for the management of infectious upper ureteral stones measuring 1–2 cm (Sun et al., 2023). A total of 173 patients were enrolled and randomized into two groups: 86 underwent retrograde intrarenal surgery (RIRS) using V-UAS, while 87 underwent MPCNL. The primary endpoint was the stone-free rate (SFR), assessed on postoperative day 1, at 2 weeks, and again at 4 weeks. Secondary outcomes included operative time, postoperative length of stay, and complication rates. The results demonstrated a statistically significant lower SFR on day 1 in the V-UAS group (73.2%) compared to the MPCNL group (86.2%) ($p = 0.034$). Although this difference resolved by the 2- and 4-week follow-ups, it raises concern about the early efficacy of V-UAS in clearing stones, especially in

infected settings where immediate decompression and clearance are critical. Furthermore, no significant differences were found in operative time or postoperative complications, suggesting that the vacuum-assisted approach may not confer clear procedural advantages in this clinical context beyond potential ease of use.

A separate randomized prospective study assessed mini-PCNL versus standard PCNL in 80 patients with renal stones ranging from 2 to 4 cm (Zeid et al., 2023). While the study did not focus on vacuum-assisted systems specifically, it evaluated outcomes associated with small-tract access similar to those used in vacuum-assisted platforms. Patients were randomized to receive either mini-PCNL (14–16 Fr tract size) or standard PCNL (30 Fr tract), with stone clearance assessed using CT urography three weeks postoperatively. The study found no significant difference in final stone-free rates between the two groups; however, the mini-PCNL group experienced significantly longer operative times and more frequent need for multiple punctures. Additionally, patients in the mini-PCNL group reported higher postoperative pain scores and greater need for analgesia. These findings suggest that the use of smaller tract sizes—often required for vacuum-assisted devices—may not always be advantageous, particularly in the treatment of larger stone burdens. The increased complexity and operative time potentially diminish the clinical efficiency of vacuum-related systems when scaled to moderate-to-large renal stones.

SUPPLEMENTAL INFORMATION

N/A

Regulatory Status

The Calyxo CVAC Aspiration System has received FDA 510(k) clearance (Class II medical device) for vacuum-assisted stone removal during ureteroscopy. However, clinicians should be aware of FDA safety communications regarding the risk of elevated intrarenal pressure when used with thick or turbid irrigation fluid, which may result in serious adverse events including infection, sepsis, or death. A redesigned version received FDA clearance in March 2024 following safety modifications.

Government Regulations

National:

There is no national coverage determination on this topic.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated

Related Policies

NA

References

1. ASPIRE Level 1 Outcomes Published Demonstrating Superior Stone Clearance with the SURE Procedure using the CVAC System vs. Standard Ureteroscopy. *BioSpace* (December 23, 2024)
2. Assimos D, et al. Initial Safety and Feasibility of Steerable Ureteroscopic Renal Evacuation: A Novel Approach for the Treatment of Urolithiasis. *Journal of Endourology*. 2023.
3. Calyxo Inc. Calyxo Announces FDA Clearance for New, Redesigned CVAC System. Calyxo Press Release. 2024.
4. Calyxo Inc. Calyxo SURE Procedure | Superior Kidney Stone Clearance. Clinical Evidence - Calyxo. 2024.
5. Ghani KR, et al. Steerable Ureteroscopic Renal Evacuation (SURE) for Large Renal Stones: A Multi-Institutional Center Study. *Journal of Urology*. 2023.
6. National Kidney Foundation. Kidney stones – Symptoms, causes, types, and treatment. National Kidney Foundation. 2024.
7. Li, J., et al. The clinical efficacy of novel vacuum suction ureteroscopic lithotripsy in the treatment of upper ureteral calculi. *World Journal of Urology* (May 17, 2021). PubMed ID: 33999260
8. Steerable Ureteroscopic Renal Evacuation (SURE) for Large Renal Stones: A Multi-Institutional Center Study. *PubMed* (August 28, 2023). PubMed ID: 37639362
9. Sun, J., Wang, W., et al. Prospective randomized comparison of vacuum-assisted ureteral access sheath (V-UAS) versus minimally invasive PCNL (MPCNL) for infectious upper ureteral stones. *Journal of Endourology*, DOI: 10.1089/end.2023.0324
10. Tuoheti, K.B., Wang, X.H., Wang, T., et al. A novel double-sheath negative-pressure versus conventional minimally invasive percutaneous nephrolithotomy for large kidney stone. *Scientific Reports* **13**, 22972 (2023). <https://doi.org/10.1038/s41598-023-50237-7>
11. U.S. Food and Drug Administration (FDA). Early Alert: Aspiration System Issue from Calyxo. FDA Safety Communication. 2024.
12. Huang J, Yang Y, Xie H, Fu Z, Zhu F, Xie L, Liu C. Vacuum-assisted dedusting lithotripsy in the treatment of kidney and proximal ureteral stones less than 3 cm in size. *World J Urol*. 2023 Nov;41(11):3097-3103. doi: 10.1007/s00345-023-04595-6. Epub 2023 Sep 12. PMID: 37698634.
13. Vacuum-assisted dedusting lithotripsy: a retrospective comparative study in high-risk patients with positive preoperative urine cultures. *PubMed* (February 17, 2025). PubMed ID: 39961857
14. Zeid, W. A., et al. Mini-percutaneous nephrolithotomy versus standard percutaneous nephrolithotomy for 2–4 cm renal stones: a prospective randomized study. *BMC Urology*, 23(1), 97 (2023). DOI: 10.1186/s12894-023-01270-1

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/25	8/19/25		New Joint policy established (de/jf) Vendor Managed: NA Literature Review

Next Review Date: 3rd Qtr, 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE

POLICY: Steerable Ureteroscopic Renal Evacuation (SURE Procedure) with Vacuum-Assisted Stone Removal Systems for Kidney Stone Management

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered with criteria
BCNA (Medicare Advantage)	See government regulation section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.