Clinical Policy Title: Extracorporeal shock wave therapies

Clinical Policy Number: 13.03.01

Effective Date: April 1, 2015
Initial Review Date: November 19, 2014
Most Recent Review Date: January 11, 2018
Next Review Date: January 2019

Related policies:

None.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of extracorporeal shock wave lithotripsy (lithotripsy) to be clinically proven and, therefore, medically necessary for urinary tract stones, including staghorn and ureteric stones (Preminger, 2007; Assimos, 2016).

Limitations:

AmeriHealth Caritas considers the inclusion of diuretics, manipulation, inversion, or alpha-blockers in the same episode of care as lithotripsy to be investigational and, therefore, not medically necessary.

All other uses of lithotripsy or shockwave therapy, including for plantar fasciitis, gallstones, and burns, are not medically necessary. Patients with recurrent calcium renal stones are eligible for a repeat lithotripsy, only with documentation of dietary or pharmacologic preventive efforts.

Centers for Medicare & Medicaid Services (CMS) limitations:
Lithotripsy, using a high- or low-dose protocol or radial wave, is considered investigational in the treatment of musculoskeletal conditions, because the safety and/or effectiveness of this therapy cannot be established by review of the available, published, and/or peer-reviewed literature. Musculoskeletal conditions include, but are not limited to:

- Plantar fasciitis.
- Tendinopathies, including tendinitis of the shoulder.
- Tendinitis of the elbow (epicondylitis, tennis elbow).
- Stress fractures.
- Delayed union and non-union of fractures.
- Avascular necrosis of the femoral head.
- Wounds including ulcers.

**Alternative covered services:**

- Percutaneous nephrostolithotomy and lithotripsy.
- Transurethral ureteroscopic lithotripsy.

**Background**

Kidney stones, also known as renal calculus, are pebble-like solid crystal aggregations formed in the kidneys from minerals in the urine. Kidney stones typically leave the body by passage in the urine stream, and many stones are formed and passed without causing symptoms. If stones grow to sufficient size (usually at least three millimeters [0.12 inches]), they can block the ureter(s). This leads to pain, most commonly beginning in the lower back and often radiating to the groin or genitals. This pain is often known as renal colic and typically comes in waves lasting 20 to 60 minutes. Additional associated symptoms include nausea, vomiting, fever, blood or pus in the urine, and painful urination.

Kidney stones are caused by not drinking enough water, limiting the ability of the body to dissolve uric acid. Some medications and supplements, such as vitamin D and calcium, can raise the risk of kidney stones. Most cases are observed in males, most commonly from ages 30 to 50. Drinking recommended amounts of water is also a precautionary measure to prevent kidney stones, along with taking certain medications.

The diagnosis of kidney stones is made on the basis of information obtained from the history, physical examination, urinalysis, and imaging studies (X-rays, CT scans, or ultrasound). Urinary stones are typically classified by their location in the kidney, ureters, or bladder, or by their chemical composition (calcium-containing, struvite, uric acid, or other compounds). About 80 percent of people with kidney stones are men. Blockage of the ureter(s) causes decreased kidney function and dilation of the kidney.

Lithotripsy is a noninvasive method of treating kidney stones with a device called a lithotripter. It uses shock waves generated outside the body to break up stones, focusing the waves on the stones by X-ray
visualization and repeated shock to pulverize them. Alternate treatments are surgical nephrotomy and transurethral ureteroscopic lithotripsy, which both remove stones using a cystoscope inserted into the ureter(s) via the bladder, and disintegrating them via mechanical crushing, electrohydraulic shock waves and/or laser.

When a stone causes no symptoms, watchful waiting is a valid option. For stones that are causing symptoms, pain control is usually the first measure, using medications such as nonsteroidal anti-inflammatory drugs or opioids. More severe cases may require procedures. For example, some stones can be shattered into smaller fragments using lithotripsy. Some cases require more invasive procedures. Examples of these are cystoscopic procedures, such as laser lithotripsy, or percutaneous techniques, such as percutaneous nephrolithotomy. Sometimes, a tube (ureteral stent) may be placed in the ureter to bypass the obstruction and alleviate the symptoms, as well as to prevent ureteral stricture after ureteroscopic stone removal (Crosta, 2017).

Lower pole stones are kidney stones in an anatomic location that has a poor rate of spontaneous clearance. Even after therapy, stone fragments may linger in this location and lead to recurrent stones.

Extracorporeal shock wave therapy is a treatment similar to lithotripsy, for certain musculoskeletal conditions. These include chronic plantar fasciitis, lateral epicondylitis (“tennis elbow”), medial epicondylitis (“golfers elbow”), hammer toe, stress fractures, and certain wounds (including ulcers).

A recent guideline of the American Urological Association consists of 56 recommendations, covering pre-operative testing for renal or ureteral stones, along with treatment for adults, pediatric patients, and pregnant women. It found that among the numerous published studies of management of kidney and ureteral stones, lithotripsy has been associated with lower morbidity and complication rates, but also a lower stone-free rate in a single procedure, compared with transurethral ureteroscopic lithotripsy (Assimos, 2016). This guideline built on findings subsequent to an earlier guideline from the European Association of Urology and American Urological Association panel, which compared the two procedures (Preminger, 2007). See appendix for lithotripsy-related recommendations in the 2016 guideline.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- CMS.

We conducted searches on November 29, 2017. Search terms were: “extracorporeal shock wave therapy” and “extracorporeal shock wave lithotripsy” [MeSH].
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

In a meta-analysis of seven randomized controlled trials (n=1,205 adults) treated for ureteric stones, researchers found that lithotripsy patients had less need for auxiliary treatment, experienced fewer complications, and had shorter hospital stays than ureteroscopy patients; however, the lithotripsy group also had higher re-treatment rates (Abourmarzouk, 2012). This review corroborated results of an earlier meta-analysis (Nabi, 2007). The most recent, and perhaps most extensive systematic review comparing ureteroscopy and lithotripsy included 47 studies, 40 percent of which were randomized controlled trials. The stone-free rate for ureteroscopy was significantly greater than lithotripsy at four weeks after the procedure, but there was no difference after three months. Ureteroscopy was associated with fewer retreatments and need for secondary procedures, but a higher need for adjunctive procedures, greater complication rates, and longer hospital stays (Drake, 2017).

A systematic review of eight controlled trials (n=876) randomized for lithotripsy patients receiving or not receiving stents found that stone-free rates were no different between the groups, but that the stented group had a higher rate of urinary tract symptoms (Shen, 2011). Other systematic reviews showed lower stone-free rates for lithotripsy patients (Matalga, 2012a; Cui, 2015; Xu, 2015). One of these reviews documented a greater likelihood of re-treatment in the lithotripsy group, with no difference in complication risk (Matalga, 2012).

The ability of lithotripsy to successfully treat urolithiasis in pediatric patients (“could be considered a first-line treatment”) was confirmed in a meta-analysis of 14 studies (n=1,842), especially when stones were less than 10 millimeters in diameter (Lu, 2015). A review of 151 papers on pediatric lithotripsy revealed limited studies on long-term effects, but widespread opinion that it does not adversely affect renal functions in the long term (Akin, 2014).

Efficacy of lithotripsy was compared with percutaneous nephrolithotomy, another means of treating kidney and ureteral stones. In an analysis of five studies (n=338), success of treatment of nephrolithotomy was superior to lithotripsy in the need for auxiliary procedure use, need for re-treatment, and efficiency quotient (Sribubat, 2014). Lithotripsy had lower stone-free rates when compared to nephrilithotomy in a 23-study (n=2,494) systematic review (Tokas, 2017).
Lower-pole stones, the most common renal calculi, are also the most likely to require treatment. One systematic review of eight controlled trials (n=691) found that lithotripsy patients had lower stone-free rates for lower-pole stones than those undergoing percutaneous nephrolithotomy and retrograde intrarenal surgery; the magnitude of the benefit was greatest for stones < 10 millimeters (Donaldson, 2015).

Long-term effects of lithotripsy were considered in one systematic review. No evidence was found that lithotripsy increased rates of arterial hypertension, diabetes mellitus, kidney dysfunction, or infertility (Fankhauser, 2015). A meta-analysis of 11 studies addressed the issue of whether lithotripsy was associated with new onset hypertension, but found no significant link (Yu, 2014).

A systematic review of six studies (n=711) compared outcomes of emergent and delayed lithotripsy for ureteral stones. Stone-free status and likelihood of need for auxiliary maneuvers were significantly lower (superior) for emergent, compared to delayed, lithotripsy (p < .001). Complication rates between emergent and delayed procedures were not significantly different (Arcaniolo, 2017).

Extracorporeal shock wave therapy for various musculoskeletal conditions has also been assessed. Systematic reviews/meta-analyses determined (low-intensity) therapy was more effective than controls in reducing heel pain and improving heel function in persons with chronic recalcitrant plantar fasciitis (Yin, 2014; Agil, 2013; Dizon, 2013). Another analysis found conflicting and limited efficacy of extracorporeal shock wave therapy in treating plantar fasciitis (Hayes, 2016).

Other large-scale reviews have focused on extracorporeal shock wave therapy for tendinitis. One found moderate evidence that it is more effective than home training and corticosteroid injection in the short and long term for greater trochanteric pain syndrome, and recommended it should be used when other non-operative approaches have failed (Mani-Babu, 2015). Others found positive results in pain reduction and functional improvement for calcific or noncalcific tendinitis of the shoulder, although the studies were heterogenous (Bannaru, 2014; Vavken, 2009).

The success of some recent procedures may reduce the need for lithotripsy. One meta-analysis of seven studies (n=902) documented that endoscopic sphincterotomy plus endoscopic papillary large balloon dilation had an effective stone clearance of 98 percent, including 87 percent after one session, indicating these can be used as a first-line technique to manage large bile duct stones (Madhoun, 2014).

Policy updates:

A total of one guideline/other and three peer-reviewed references were added, and three peer-reviewed references removed, from this clinical policy in November 2017.

Summary of clinical evidence:
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Drake (2017) | **Key points:**  
- Systematic review of ureteroscopy and lithotripsy of 47 studies on upper ureteral stones.  
- 39.6% of studies were randomized controlled trials.  
- The stone-free rate for ureteroscopy was significantly greater than lithotripsy at four weeks after the procedure, but there was no difference after three months.  
- Ureteroscopy was associated with fewer retreatments and need for secondary procedures, but a higher need for adjunctive procedures, greater complication rates, and longer hospital stay. |
| Tokas (2016) | **Key points:**  
- Systematic review of 23 studies (n=2,494), stone-free rates.  
- For six lithotripsy studies, stone-free rates ranged from 35.0% – 61.3%.  
- For five retrograde intrarenal surgery studies, stone-free rates ranged from 34.8% – 59.7%.  
- For eight percutaneous nephrolitholapaxy studies, stone-free rates ranged from 20.8% – 100%.  
- Percutaneous nephrolitholapaxy had better stone-free rates. |
| Fankhauser (2015) | **Key points:**  
- Systematic review of 30 studies on long-term effects of lithotripsy versus ureterolithiasis.  
- No elevation in lithotripsy rates of arterial hypertension (24/30 studies); diabetes mellitus (4/6); kidney dysfunction (14/14); infertility (2/2).  
- No strong evidence exists to support lithotripsy causes long-term adverse events. |
| Mani-Babu (2015) | **Key points:**  
- Systematic review of studies on extracorporeal shock wave therapy, 13 studies included.  
- Extracorporeal shock wave therapy more effective (long- and short-term) than home training and corticosteroid injection.  
- Extracorporeal shock wave therapy more effective than non-steroidal anti-inflammatory drugs, physical therapy, and an exercise program, but evidence is limited.  
- Extracorporeal shock wave therapy should be considered for greater trochanteric pain syndrome, patellar tendinopathy, and Achilles tendinopathy. |
| Madhoun (2014) | **Key points:**  
- Comparative studies, 1994 – 2013, on reducing need for mechanical lithotripsy in large bile duct stones.  
- Seven studies (n=406); three of seven prospective, but no further method details reported.  
- Endoscopic sphincterotomy (ES) differences: appears safe, further research needed. |
| Aboumarzouk (2012) | **Key points:**  
- Seven trials (n=1,205), 1966 – 2011.  
- Lithotripsy had less need for auxiliary treatment, complications, shorter LOS.  
- Ureteroscopy had lower stone-free rates; re-treatment rates. |
| Matalga (2012) | **Key points:**  
- Systematic review/meta-analysis, 13 studies (ureteroscopy versus lithotripsy).  
- Ureteroscopy = 55% greater chance of stone-free status than lithotripsy, distal ureteral stones.  
- Ureteroscopy = more likely to require re-treatment.  
- Ureteroscopy = risk of complications no different than lithotripsy. |
References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**

L35627 Extracorporeal Shock Wave Lithotripsy for Musculoskeletal Conditions. CMS Medicare Coverage Database website. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35627&ver=12&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=lithotripsy&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAAA%3d%3d&. Accessed November 29, 2017.](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35627&ver=12&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=lithotripsy&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAAA%3d%3d&)

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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Appendix

Excerpts from Assimos D, Krambeck A, Miller NL, et al. Surgical management of stones: American Urological Association/Endourological Society guideline, August 2016. Of 56 statements in the guideline, the following are pertinent to extracorporeal shock wave therapies.

Note: SWL is an abbreviation for shock wave lithotripsy, URS denotes transurethral ureteroscopic lithotripsy.

Statement 10: Clinicians should inform patients that SWL is the procedure with the least morbidity and lowest complication rate, but URS has a greater stone-free rate in a single procedure. (Index Patients 1-6) Strong Recommendation; Evidence Level Grade B

Statement 11: Inpatients with mid or distal ureteral stones who require intervention (who were not candidates for or who failed MET), clinicians should recommend URS as first-line therapy. For patients who decline URS, clinicians should offer SWL. (Index Patients 2, 3, 5, 6) Strong Recommendation; Evidence Level Grade B

Statement 13: Routine stenting should not be performed in patients undergoing SWL. (Index Patients 1-6) Strong Recommendation; Evidence Level Grade B

Statement 21: In symptomatic patients with a total non-lower pole renal stone burden ≤ 20 mm, clinicians may offer SWL or URS. (Index Patient 7) Strong Recommendation; Evidence Level Grade B

Statement 22: In symptomatic patients with a total renal stone burden >20 mm, clinicians should offer PCNL as first-line therapy. (Index Patient 8) Strong Recommendation; Evidence Level Grade C

Statement 25: In patients with total renal stone burden >20 mm, clinicians should not offer SWL as first-line therapy. (Index Patient 8) Moderate Recommendation; Evidence Level Grade C

Statement 30: Clinicians should offer SWL or URS to patients with symptomatic ≤ 10 mm lower pole renal stones. (Index Patient 9) Strong Recommendation; Evidence Level Grade B

Statement 31: Clinicians should not offer SWL as first-line therapy to patients with >10 mm lower pole stones. (Index Patient 10) Strong Recommendation; Evidence Level Grade B

Statement 47: Clinicians should offer URS or SWL for pediatric patients with ureteral stones who are unlikely to pass the stones or who failed observation and/or MET, based on patient-specific anatomy and body habitus. (Index Patient 13) Strong Recommendation; Evidence Level Grade B

Statement 51: In pediatric patients with a total renal stone burden >20 mm, both PCNL and SWL are acceptable treatment options. If SWL is utilized, clinicians should place an internalized ureteral stent or nephrostomy tube. (Index Patient 14) Expert Opinion