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 18, 2017
Next Review Date: January 2018

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s 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 Keystone First 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. Keystone First’s 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. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of extracorporeal shock wave lithotripsy (ESWL) to be clinically proven and, therefore, medically necessary for urinary tract stones, including staghorn and ureteric stones.

Limitations:

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

All other uses of ESWL 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 ESWL, only with documentation of dietary or pharmacologic preventive efforts.
Centers for Medicare & Medicaid Services (CMS) limitations:

ESWL, 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 3 millimeters (0.12 in)] they can cause blockage of 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.

The diagnosis of kidney stones is made on the basis of information obtained from the history, physical examination, urinalysis, and imaging studies (X-rays 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. ESWL is a noninvasive method of treating kidney stones with a device called a lithotriptor. 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 ESWL. 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.

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.

ESWT 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).

Searches

Keystone First 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.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on November 18, 2016. 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
A recent guideline of the American Urological Association found that among the numerous published studies of management of kidney and ureteral stones, ESWL 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 ESWL-related recommendations in the 2016 guideline.

In a meta-analysis of seven randomized controlled trials (RCTs) covering 1205 adults treated for ureteric stones, researchers found that ESWL patients had less need for auxiliary treatment, experienced fewer complications, and had shorter hospital stays than ureteroscopy patients; however, the ESWL group also had higher re-treatment rates (Abourmarzouk 2012). This review corroborated results of an earlier meta-analysis (Nabi 2007).

A systematic review of eight controlled trials covering 876 patients randomized for ESWL 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 ESWL patients (Matalga 2012a, Cui 2015, Xu 2015). One of these reviews documented a greater likelihood of re-treatment in the ESWL group, with no difference in complication risk (Matalga 2012a). The ability of ESWL to successfully treat urinary stones in pediatric patients (“could be considered a first-line treatment”) was confirmed in a meta-analysis of 14 studies (n=1842), especially when stones were less than 10 mm. in diameter (Lu 2015).

Efficacy of ESWL was compared with percutaneous nephrolithotomy (PCNL), another means of treating kidney and ureteral stones. In an analysis of five studies with 338 patients, success of treatment of PCNL was superior to ESWL in terms of need for auxiliary procedure use, need for re-treatment, and efficiency quotient (Srisubat 2014). ESWL had lower stone-free rates when compared to PCNL in a 24-study systematic review (Tokas 2016).

Lower-pole stones, the most common renal calculi, are also the most likely to require treatment. One systematic review of seven controlled trials (n=691) found that ESWL 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 mm (Donaldson 2015).

Long-term effects of ESWL were considered in one systematic review. No evidence was found that ESWL increased rates of arterial hypertension, diabetes mellitus, kidney dysfunction, or infertility (Fankhauser 2015).

Economic analysis was the subject of a meta-analysis comparing ureteroscopy patients with ESWL patients. In four of five studies, ureteroscopy was found to be less costly by about $2,500 per treatment than ESWL (Matalga 2012b).
Extracorporeal shock wave therapy (ESWT) 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 ESWT in treating plantar fasciitis (Hayes 2016).

Other large-scale reviews have focused on ESWT 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).

Policy updates:

A total of five guidelines/other references and 15 peer-reviewed references were added to this clinical policy in November 2016, most of which were meta-analyses, systematic reviews, or recent publications.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tokas (2016)</td>
<td>Stone free rates for ESWL and other interventions</td>
</tr>
<tr>
<td>Key points:</td>
<td>• Systematic review of 23 studies (n=2494), stone free rates.</td>
</tr>
<tr>
<td></td>
<td>• For 6 ESWL studies, SFR ranged from 35.0-61.3%.</td>
</tr>
<tr>
<td></td>
<td>• For 5 retrograde intrarenal surgery studies, SFR ranged from 34.8-59.7%.</td>
</tr>
<tr>
<td></td>
<td>• For 8 percutaneous nephrolitholapaxy studies, SFR ranged from 20.8-100%.</td>
</tr>
<tr>
<td></td>
<td>• Percutaneous nephrolitholapaxy had better SFRs.</td>
</tr>
<tr>
<td>Fankhauser (2015)</td>
<td>Assessment of long term adverse effects, ESWL vs. ureterolithiasis</td>
</tr>
<tr>
<td>Key points:</td>
<td>• Systematic review of literature on long term effects of ESWL vs. ureterolithiasis.</td>
</tr>
<tr>
<td></td>
<td>• No elevation in ESWL rates of arterial hypertension (24/30 studies); diabetes mellitus (4/6); kidney dysfunction (14/14); infertility (2/2).</td>
</tr>
<tr>
<td></td>
<td>• No strong evidence exists to support ESWL causes long term adverse events.</td>
</tr>
<tr>
<td>Mani-Babu (2015)</td>
<td>Effectiveness of lower limb tendinopathies for ESWT</td>
</tr>
<tr>
<td>Key points:</td>
<td>• Systematic review of studies on EWST, 13 studies included.</td>
</tr>
<tr>
<td></td>
<td>• EWST more effective (long- and short-term) than home training and corticosteroid injection.</td>
</tr>
<tr>
<td></td>
<td>• ESWT more effective than non-steroidal anti-inflammatory drugs, physical therapy, and an exercise program, but evidence is limited.</td>
</tr>
<tr>
<td></td>
<td>• ESWT should be considered for greater trochanteric pain syndrome, patellar tendinopathy, and Achilles tendinopathy.</td>
</tr>
<tr>
<td>Madhoun (2014)</td>
<td>Endoscopic large balloon dilation vs. endoscopic</td>
</tr>
<tr>
<td>Key points:</td>
<td>• Comparative studies, 1994 – 2013, on reducing need for mechanical lithotripsy in large bile duct stones.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------</td>
</tr>
</tbody>
</table>
| sphincterotomy | - Seven studies (n=406); three of seven prospective, but no further method details reported.  
- Endoscopic sphincterotomy (ES) differences: appears safe, further research needed. |
| Yin (2014) | **Key points:**  
- Seven trials (550 subjects): small trials but quality not otherwise reported.  
- Low intensity more effective than controls for short-term pain relief and function. |
| Chronic plantar fasciitis | **Key points:**  
- Seven trials (1,205 subjects), 1966 – 2011.  
- ESWL had less need for auxiliary treatment, complications, shorter LOS.  
- Ureteroscopy had lower stone-free rates; re-treatment rates. |
| Aboumarzouk(2012) | **Key points:**  
- Systematic review/meta-analysis, 13 studies (ureteroscopy vs. ESWL).  
- Ureteroscopy = 55% greater chance of stone-free status than ESWL, distal ureteral stones.  
- Ureteroscopy = more likely to require re-treatment.  
- Ureteroscopy = risk of complications no different than ESWL. |
| ESWL vs. ureteroscopy for ureteric stones | **Key points:**  
- Percutaneous nephrolithotomy should be the first treatment for most patients, except when combination therapies are used (it should be the last).  
- ESWL monotherapy requires drainage of treated unit be established in advance.  
- Open surgery by any method should be avoided for most patients. |
| AUA (2010) | **Key points:**  
- Stones <10 mm stone-free were superior for URS (85% vs. 66.5% for proximal ureteral stones; 91% vs. 75% for middle ureteral stones; 94% vs. 74% for distal ureteral stones).  
- Stones >10 mm stone-free were superior for URS (79% vs. 74% in the proximal ureter; 82.5% vs. 67% for mid ureteral stones; 92% vs. 71% for distal ureteral stones).  
- Average number of URS procedures to treat proximal, middle, and distal ureter were 1.01, 1.00 and 1.00 for URS, 1.34, 1.29, and 1.26 for ESWL. |

**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 Web site. [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=gAAAAACAAAAAAA%3d%3d&](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=gAAAAACAAAAAAA%3d%3d&). Accessed November 22, 2016.
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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>50590</td>
<td>Lithotripsy, extracorporeal shock wave</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>N20.0</td>
<td>Calculus of kidney</td>
<td></td>
</tr>
<tr>
<td>N20.1</td>
<td>Calculus of ureter</td>
<td></td>
</tr>
<tr>
<td>N20.2</td>
<td>Calculus of kidney with calculus of ureter</td>
<td></td>
</tr>
<tr>
<td>N20.9</td>
<td>Urinary calculus, unspecified</td>
<td></td>
</tr>
<tr>
<td>N22</td>
<td>Calculus of urinary tract in diseases classified elsewhere</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>S0400</td>
<td>Global fee for extracorporeal shock wave lithotripsy treatment of kidney stone(s)</td>
<td></td>
</tr>
</tbody>
</table>

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: In patients 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 >10mm 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 >20mm, 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*