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 20, 2016
Next Review Date: January, 2017

Related policies:

None.

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

Coverage policy

Arbor Health Plan 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:

Arbor Health Plan 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.

Note: The following CPT/HCPCS code is not listed in the Nebraska Medicaid fee schedule:

S0400 - Global fee for extracorporeal shock wave lithotripsy treatment of kidney stone(s)

**Alternative covered services:**

Surgical or ureteroscopic stone removal, according to individual patient circumstances.

**Background**

ESWL 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 lithrotripsy, 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.

Extracorporeal shock wave therapy (ESWT) is a treatment for musculoskeletal conditions, such as chronic plantar fasciitis or lateral epicondylitis, which is similar to lithotripsy.

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.

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.

Lateral epicondylitis is also known as “tennis elbow.”

**Searches**

Arbor Health Plan 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 30, 2015. Search terms were: “extracorporeal shock wave therapies” 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**

**Urinary tract stones**

- The evidence base for lithotripsy has improved substantially since Canadian Agency for Drugs and Technologies in Health (CADTH) (2009) found barely enough high-quality evidence to support recommendations.
- Stones can occur in sites other than the urinary tract, including the salivary glands, pancreatic duct, and/or gallbladder. However, the majority of systematic reviews and the single-indexed CMS coverage document identified for this policy, focus on urinary tract stones. ESWL and other minimally invasive approaches have become the treatments of choice for these stones, and open surgery is now an infrequently used option (CADTH, 2009).
- Adjuncts to, or combinations of, ESWL with other approaches (manipulation, dieresis, inversion, tamulosin/other alpha-blockers) are explored in several reviews (tabulated in the summary of clinical evidence table below), which are insufficient to support any of these options on a routine basis.
- No single stone removal strategy is optimal for all stone sizes or locations within the urinary tract; urologists will need to combine experience with evidence in choice of procedure.

**Musculoskeletal conditions**

- ESWT for musculoskeletal conditions is represented by only a few systematic reviews, most of which identified small trials too heterogeneous for meta-analysis.
- CMS considers ESWT not medically necessary for musculoskeletal conditions.

**Policy updates:**

Updated National Coverage Determination (NCD), effective October 1st, 2015; CMS limitations for ESWT.

**Summary of clinical evidence (kidney stones):**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Madhoun MF, et al. (2014) Endoscopic large balloon dilation vs. endoscopic sphincterotomy to reduce need for mechanical lithotripsy in large bile duct | **Key points:**
| | - Seven studies (406 subjects); three of seven prospective, but no further method details reported.
<p>| | - Endoscopic sphincterotomy (ES) differences: appears to be safe but further research |</p>
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>stones</td>
<td>needed.</td>
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</table>
| Niu (2014) New-onset hypertension after ESWL | **Key points:**  
- Eleven case-control and cohort studies.  
- No significant association. |
| Fink, Agency for Healthcare Research and Quality (AHRQ) (2013) Prevention of recurrent kidney stones | **Key points:**  
- Twenty-eight randomized controlled trials (RCTs) (eight dietary interventions; 28 pharmacological) 27 of fair quality.  
- Increased fluid intake, reduced soft drink consumption, thiazide diuretics, citrate pharmacotherapy, and allopurinol, reduce risk of recurrent calcium stones.  
- Mixed/inconsistent results for other dietary interventions.  
- No RCTs for uric acid or cystine stones. |
| Liu, Cochrane (2013) Percussion, diuresis, and inversion therapy after ESWL for lower pole stones | **Key points:**  
- Insufficient evidence. |
| Aboumarzouk, Cochrane (2012) ESWL vs. ureteroscopy for ureteric stones | **Key points:**  
- Seven trials (1,205 subjects).  
- In favor of ESWL: less need for auxiliary treatment, complications, length of hospital stay (LOS).  
- Ureteroscopy: stone-free rates; re-treatment rates.  
- All studies had conduct or reporting shortcomings, leading to unclear risks of bias.  
- Conclusions: Ureteroscopic removal of stones in the ureter achieves higher stone-free state, but with more complications and longer LOS. |
| Koo (2011) Cost-effectiveness vs. ureteroscopic holmium:yttrium-aluminium-garnet laser for lower pole stones | **Key points:**  
- Analysis based on one study: UK outpatient academic clinic patients without anesthesia or sedation, and lower pole stones ≤ 20mm.  
- ESWL clinically effective and cost-effective; ureteroscopy more expensive and no significant (NS) difference clinically. |
| American Urological Association (AUA) (2010) Staghorn calculi | **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 that adequate drainage of the treated unit be established in advance.  
- Open surgery by any method should be avoided for most patients. |
<table>
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</thead>
</table>
| European Association of Urology, American Association of Urology (EAU/AUA) (2010) Ureteral calculi | **Key points:**  
  - Stones < 10 mm and controlled symptoms: observation with periodic evaluation and medical therapy to facilitate stone passage should be an option.  
  - Stones > 10 mm and requiring removal: ESWL and ureteroscopy are acceptable first-line options.  
  - Laparoscopic or open surgical removal may be considered where other options fail, or success is unlikely.  
  - Children: treatment should be based on size and urinary tract anatomy, although small ureter and urethra favor less invasive approaches. |
| CADTH (2009) Lithotripsy for kidney or gall stones | **Key points:**  
  - RCTs, economic analyses, systematic reviews, 2004 – 9.  
  - Kidney: Significantly better stone-free rates with ESWL than surgery.  
  - Gall stones: ESWL should be considered for patients with difficult common bile duct stones who are not candidates for open surgery. |
| Losek (2008) Tamsulosin with ESWL | **Key points:**  
  - Insufficient evidence. |
| Seitz (2009) Medical therapy to facilitate passage of stones | **Key points:**  
  - Alpha-blockers or calcium-channel blockers, with or without previous ESWL.  
  - Insufficient evidence. |
| Srisubat, Cochrane (2009) vs. percutaneous nephrolithotomy or retrograde surgery for kidney stones | **Key points:**  
  - Three small low-quality studies (204 subjects): ESWL less effective than percutaneous for lower pole stones, but not significantly different than retrograde.  
  - More RCTs directly comparing options are needed. |
| Hayes (2006) Erbium: YAG laser for lithotripsy of salivary stones | **Key points:**  
  - Annotated bibliography without explicit evidence analysis.  
  - Update of archived 2000 directory publication: no major changes.  
  - Insufficient evidence. |
| Varkarakis (2003) Outcomes and costs in situ and after manipulation. | **Key points:**  
  - Patients treated for a single proximal ureteral stone (0.5 – 2 cm), January 1999 – Feb 2001; secondary care in Athens, Greece.  
  - Costs and outcomes from the same RCT: power calculation and sample accrual methods not reported.  
  - Manipulation less effective, more costly and with higher rate of infections than in situ at one, two and three months, but no overall summary benefit measure calculated or reported. |
Summary of clinical evidence (musculoskeletal conditions):

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</table>
| Bannuru (2014) Chronic calcific tendinitis of the shoulder | **Key points:**  
  - Twenty-eight trials (1,745 subjects).  
  - Narrative synthesis as heterogeneity precluded meta-analysis.  
  - High-energy ESWT is effective, but under-utilized. |
| Yin (2014) Chronic plantar fasciitis | **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. |
| Hayes (2013) Chronic plantar fasciitis | **Key points:**  
  - Hayes B: consistent evidence for high-energy treatment in patients with $\geq$ six months duration, who have failed conservative therapy.  
  - Unresolved questions re: comparison with surgical therapy, optimal treatment parameters and contraindications (pregnancy, bleeding tendencies). |
| Buchbinder (Cochrane; 2009) Elbow pain | **Key points:**  
  - Nine trials (1,000 subjects with tennis elbow).  
  - ESWT no better than placebo. |

**Glossary**

**Diuresis** — Therapy to increase urine flow to facilitate the passing of kidney stones.

**Inversion therapy** — Placing the patient at an inverted angle.

**Nonsteroidal anti-inflammatory drugs (NSAIDs)** — A class of drugs with both analgesic and anti-inflammatory effects. NSAIDs include ibuprofen (Advil) and naproxen (Aleve), both of which are available over the counter in the United States. They are used for acute and chronic conditions involving pain and inflammation, such as osteoarthritis, rheumatoid arthritis, low back pain, headache, renal colic and toothache. Since gastrointestinal side effects are prominent, they should be avoided by people with dyspepsia or other existing gastrointestinal conditions, such as diarrhea or bleeding.

**Percussion** — Striking or tapping the body, usually with a device (percussor).

**Percutaneous** — Through the skin, referring to surgery with access to underlying structures through a skin incision.
Staghorn calculi — A large stone that takes up more than one branch of the collecting system in the renal pelvis.
Tamsulosin — A drug used in the treatment of difficult urination due to an enlarged prostate. Tamsulosin, and other medications in the class called alpha blockers, work by relaxing bladder neck muscles and muscle fibers in the prostate, making it easier to urinate.

References

Professional society guidelines/others:


Hayes, Inc. Lithotripsy for salivary stones. Annual Review. 8/11/06.

Peer-reviewed references:


**Clinical trials:**
Searched clinicaltrials.gov on November 30, 2015 using terms “extracorporeal shockwave lithotripsy” | Open Studies. Four studies found, three relevant.


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


**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.


**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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<table>
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<tr>
<td>N20.1</td>
<td>Calculus of ureter</td>
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<tr>
<td>N20.2</td>
<td>Calculus of kidney with calculus of ureter</td>
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<td>N20.9</td>
<td>Urinary calculus, unspecified</td>
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<tr>
<td>N22</td>
<td>Calculus of urinary tract in diseases classified elsewhere</td>
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<tr>
<th>HCPCS Level II</th>
<th>Description</th>
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<td>S0400</td>
<td>Global fee for extracorporeal shock wave lithotripsy treatment of kidney stone(s)</td>
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