Name of Policy: 
Extracorporeal Shock Wave Lithotripsy of Renal Stones

Policy #: 002  
Category: Surgical  
Latest Review Date: July 2010  
Policy Grade: Effective June 14, 2010:  
Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Extracorporeal shock wave lithotripsy (ESWL) is a non-invasive treatment option for the management of kidney or ureteral stones. Other options include expectant management (particularly for small stones), percutaneous antegrade nephrostoureterolithotomy, retrograde ureteroscopy with or without intracorporeal lithotripsy, laparoscopic ureterolithotomy, and open ureterolithotomy. The choice of treatment is primarily based on size, location, and composition of the stone. ESWL consists of high-intensity shock waves that are produced electrically, and focused radiographically or ultrasonically on the treatment area. More than one treatment may be required. General, spinal, or epidural anesthesia is usually administered with this procedure.

Following ESWL, most kidney stone fragments are eventually eliminated in the urine. Adjunctive procedures (e.g., pre-ESWL stent placement or stone manipulation, and post-ESWL endoscopy or surgery) are estimated to be required in 7%–15% of patients to ensure the complete removal of the stone fragments.

**Policy:**
Extracorporeal Shock Wave Lithotripsy meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all the following criteria are met:

1. Renal-calyceal stone is no smaller that 3 mm in diameter. These stones are not normally symptomatic while calyceal.
2. No more than three stones present. Procedures for more than three stones will be considered with documentation of medical necessity.
3. Stones result in pain, inability to void, and/or nausea and vomiting.
4. Stone is not likely to pass spontaneously without significant adverse symptoms.
5. Uncontrolled infections are managed.
6. Renal tract obstructions (not related to the stone) are corrected.
7. Stone can be visualized after imaging study.
8. Patient anatomy allows for proper focusing of the shock wave. (May not be possible in very obese patients)
9. Treated kidney is functional.
10. Absence of any signs of renal artery calcification or aneurysm.
11. Absence of aortic or iliac calcification near a ureteral stone.

Stones up to 2 cm. are generally treated in a single procedure. Stones greater than 2 cm or extremely dense stones less than 2 cm may require multiple procedures.

ESWL should be used with extreme caution in pregnant women, children, and patients with cardiac pacemakers.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best
medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
“Urinary stones usually arise because of the breakdown of a delicate balance. The kidneys must conserve water, but they must also excrete materials that have a low solubility. These two opposing requirements must be balanced during adaptation to diet, climate, and activity. The problem is mitigated to some extent by the fact that urine contains substances that inhibit crystallization of calcium salts and others that bind calcium in soluble complexes. These protective mechanisms are less than perfect. When the urine becomes supersaturated with insoluble materials, because excretion rates are excessive and/or because water conservation is extreme, crystals form and may grow and aggregate to form a stone”. (Isselbacher et al)

The management of stones present in the kidneys or urinary tract requires a combined medical and surgical approach. Treatment depends on the location of the stone, the extent of obstruction, the function of the affected and unaffected kidneys, the passage and the risk of operation or anesthesia to the patient. Severe obstructions, infection, intractable pain, and serious bleeding are indications for removal of a stone.

There are three methods for removing stones. Extracorporeal lithotripsy, cause the in situ fragmentation of stones in the kidney, renal pelvis, or proximal ureter by exposing them to shock waves. “The patient is submerged in a water tank, the kidney with the stone is centered at the focal point of parabolic reflectors, and high-intensity shock waves are created by high-voltage discharge. The reflectors focus the waves so that they pass through the patient and fracture the stone as they pass. After multiple discharges, most stones are reduced to a powder that moves through the ureter into the bladder. Larger fragments are removed by cystoscopy.” (Isselbacher et al) Stones may also be removed by percutaneous ultrasonic lithotripsy. If ESWL or percutaneous ultrasonic lithotripsy cannot remove stones, an ultrasonic transducer is passed into the ureter via cystoscope; stones are fragmented and then removed.

**Key Words:**
ESWL; lithotripsy; extracorporeal shock wave for kidney stones; removal of kidney stones; renal calculi

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification requirements: Subject to contract language
Current Coding:
CPT Codes:

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<tr>
<th>Code</th>
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<tr>
<td>50590</td>
<td>Lithotripsy, Extracorporeal shock wave</td>
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References:

Policy History:
TEC Manual, December 1988
Medical Policy Group, July 2001
Medical Policy Administration Committee, July 2001
Medical Policy Group, July 2004 (2)
Medical Policy Administration Committee, July 2004
Available for comment July 9-August 23, 2004
Medical Policy Group, July 2007 (1)
Medical Policy Group, July 2010 (1): Active Policy but no longer scheduled for regular literature reviews and updates effective June 14, 2010
Medical Policy Group, October 2013 (1): Removed ICD-9 Diagnosis/Procedure codes; Removed Medical Policy Reference Manual, removed code 52353 from coding section, not related to this policy; no change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims, (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.