LITHOTRIPSY FOR SALIVARY STONES

Policy Number: 2014T0247K
Effective Date: October 1, 2014

Table of Contents

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENEFIT CONSIDERATIONS</td>
<td>1</td>
</tr>
<tr>
<td>COVERAGE RATIONALE</td>
<td>2</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>2</td>
</tr>
<tr>
<td>DESCRIPTION OF SERVICES</td>
<td>2</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>2</td>
</tr>
<tr>
<td>U.S. FOOD AND DRUG ADMINISTRATION</td>
<td>5</td>
</tr>
<tr>
<td>CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)</td>
<td>5</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>5</td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>6</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
COVERAGE RATIONALE

Extracorporeal shock wave lithotripsy (ESWL) is unproven and not medically necessary for the treatment of salivary stones.

There is insufficient evidence to support the use of ESWL for managing salivary stones. Further research with randomized controlled studies is required to demonstrate the effectiveness of ESWL.

Endoscopic intracorporeal laser lithotripsy is unproven and not medically necessary for the treatment of salivary stones.

The evidence regarding intracorporeal laser lithotripsy is limited and includes studies involving a small number of patients. Further research with randomized controlled studies and larger patient sample sizes is required to demonstrate the effectiveness of endoscopic intracorporeal laser lithotripsy.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>42699</td>
<td>Unlisted procedure, salivary glands or ducts</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

DESCRIPTION OF SERVICES

Salivary glands, located near the mouth and throat, secrete saliva into the mouth aiding in digestion, moistening the mouth and protecting teeth from decay. The major salivary glands include the submandibular, sublingual and parotid glands.

Sialolithiasis, the formation of salivary stones due to crystallization of minerals in saliva, can cause blockage of salivary ducts resulting in painful inflammation, especially during or after meals. Most salivary stones occur in the submandibular gland, followed by the parotid gland and infrequently in the sublingual or minor salivary glands. While smaller stones may pass on their own, larger stones generally require medical or surgical intervention. Surgery, however, carries risks, such as possible injury to the facial nerves. Therefore, minimally invasive and nonsurgical techniques of treating salivary stones have been evolving rapidly.

Extracorporeal shock wave lithotripsy (ESWL) is one minimally invasive approach that uses high energy shock waves generated outside the body to pulverize or crush the stones inside the body. Intracorporeal laser lithotripsy, with the guide of a flexible endoscope, has also been proposed to treat salivary stones. In this procedure, a pulsed dye laser is used to fragment the salivary stones inside the body. Higher energy levels may be used without causing adjacent tissue injury since delivery is pulsed, or intermittent, reducing the risk of excessive thermal build-up that is possible with a continuous laser.

CLINICAL EVIDENCE

Desmots et al. (2013) evaluated the predictive value of sonographic fragmentation in the treatment of sialolithiasis. The main objective was to streamline the management by treating the
patients with three sessions of ultrasonic lithotripsy, and to compare the success rate and complications with data from the literature. A second objective was to analyze the predictive value of data from the post procedure and follow-up sonography related to therapeutic success with regard to size, site and location of stones. The study methods included a prospective follow-up of 25 patients over a period of 31 months with one or more salivary calculi (19 parotid, submandibular 6) treated with extracorporeal lithotripsy (electromagnetic MINILITH SL 1, Storz Medical, Switzerland). No anaesthesia or analgesia was used. Each session of lithotripsy lasted on average 30 min. Complete success (absence of clinical symptoms 3 months after the end of treatment (or the last session) and residual stones <2 mm) was observed in 36% of patients, partial success (persistence of symptoms least 3 months (lower intensity and lower frequency) or size of residual stones>2 mm) in 48% and failure (persistence of same or increased symptoms at 3 months or no change in size of the calculi) in 17% of patients. Sonographic fragmentation of the stone, total energy delivered and the total number of shock waves are predictive factors of complete success. Size, salivary topography, ductal topography, mobilization of the stones, occurrence of minor side effects and total duration of treatment had no predictive value of complete success. There was no significant difference between the first 5 and the last 20 patients. In agreement with the literature data, the efficacy of treatment was greater for parotid than submandibular calculi. The authors concluded that extracorporeal lithotripsy is an alternative to conventional surgery with no major complications. Sonographic fragmentation of calculi, total energy and total number of shock waves are predictive factors of successful treatment. This study is limited by lack of a control group and small study population.

Phillips and Withrow (2014) compared outcomes and complication rates of sialolithiasis treated with intracorporeal holmium laser lithotripsy in conjunction with salivary endoscopy with those treated with simple basket retrieval or a combined endoscopic/open procedure. Thirty-one patients were treated for sialolithiasis. Sialoliths averaged 5.9 mm in size and were comparable between both groups. Sixty-eight percent were in the submandibular gland (n = 21), with the remaining 32% in the parotid gland (n = 10). Fifty-two percent of patients (n = 16) were treated endoscopically with intracorporeal holmium laser lithotripsy, while the remaining 48% (n = 15) were treated with salivary endoscopy techniques other than laser lithotripsy. Successful stone removal without additional maneuvers occurred in 81% of the laser cases and 93% of the non-laser group. Patients in the laser group reported an average improvement of symptoms of 95% compared with 90% of the non-laser group when adjusted for outliers. Complications in all patients included ductal stenosis (n = 2) and salivary fistula (n = 1). According to the authors, the results of this study show favorable outcomes with the use of intracorporeal holmium laser lithotripsy for the endoscopic management of sialolithiasis with minimal adverse events. This study was uncontrolled and had a small sample size.

Zenk et al. (2012) conducted a case series with chart review of 1154 patients with sialolithiasis. Diagnostic sialendoscopy confirmed 221 parotid stones and 812 submandibular stones, of which 206 and 736, respectively, were treated. Transoral stone removal was the most frequently used method to remove submandibular stones (92%). Parotid stones were removed by salivary gland endoscopy (SGE) (22%), combined SGE and incisional technique (26%), or extracorporeal shockwave lithotripsy (ESWL) (52%), with long-term success rates of 96%, 89%, and 79%, respectively. The authors concluded that salivary gland endoscopy is an important diagnostic and therapeutic tool in the management of sialolithiasis but must be combined with additional techniques to ensure a high rate of stone clearance, symptom resolution, and gland preservation. Study limitations included no randomization or blinding and a lack of a controlled comparator group. There was no diagnostic reference standard so a comparison between different removal methods was not possible.

Iro et al. (2009) evaluated the application of minimally invasive techniques in the management of salivary stones. The observational study included 4,691 patients (parotid n = 1,165, submandibular n = 3,526) for analysis. Extracorporeal shock wave lithotripsy (ESWL) was the primary treatment in 2,102 patients. Complete success of ESWL was achieved in 1,072 out of 2,102 patients (50.9%), the proportion differing between sites (submandibular 557 out of 1,364
(40.8%); parotid 515 out of 738 (69.8%). The technique was partially successful in a 1030 patients (49.1%) of whom 248 patients went on to be treated by other minimally invasive methods. Of these, half were submandibular and a quarter were parotid stones. A total of 1522 patients underwent basket or microforceps retrieval as first line intervention and complete success was achieved in 91.6% of patients. A total of 1021 patients underwent intraoral surgery as first line intervention and complete success was achieved in 93% of patients. These outcomes were assessed 3 to 6 months after completion of treatment. This study is limited by lack of a control group and short-term follow-up.

In a prospective controlled trial, Escudier et al. (2010) identified the factors that affect outcome (stone clearance, partial clearance without symptoms, and residual stone with symptoms unchanged) of extracorporeal shock wave lithotripsy (ESWL). The study included 142 salivary calculi (78 submandibular, 64 parotid). The results were analyzed and a predictive model generated, which was validated using a second group of patients treated by the same technique. ESWL achieved complete success (stone and symptom free) in 67 (47.15%) of cases (submandibular 28/78, 35.9%; parotid 39/64, 60.9%). Partial success (residual stone and symptom free) was obtained in a further 49 (34.5%) (submandibular 29/78, 37.2%; parotid 20/64, 31.3%). Failure occurred in 26 (18.3%) of cases (submandibular 21/78, 26.9%; parotid 5/64, 7.8%). The investigators concluded that ESWL can eradicate salivary calculi but its effectiveness is dependant mainly on size of the stone. This study is limited by lack of long-term follow-up.

In a retrospective analysis, Schmitz, et al. (2008) observed 167 patients over 7 years. Successful treatment with total stone disintegration was achieved in 51 (31 per cent) patients. In 92 (55 per cent) patients, treatment was partially successful, with disappearance of the symptoms but a sonographically still identifiable stone. Treatment failure occurred in 24 (14 per cent) patients who then underwent surgery. The mean follow-up period was 35.6 months (minimum three, maximum 83), after which 83.2 per cent of the initially successfully treated patients were still free of symptoms.

McGurk et al. (2005) studied 455 salivary calculi that were treated by ESWL, fluoroscopically guided basket retrieval or intraoral stone removal. The techniques were used alone or in combination. ESWL resulted in complete success in 87 (39.4%) of 221 patients (84 of 218 primary and all of 3 secondary procedures; 43 of 131 submandibular and 44 of 90 parotid).

Capaccio et al. (2004) conducted a consecutive patient series that assessed 322 patients with salivary calculi who underwent electromagnetic ESWL. Complete elimination of the stone was accomplished in 45% of patients. Residual fragments (less than 2 mm in diameter) were detected by ultrasound in 27.3% of patients, and persisting fragments greater than 2 mm in diameter were found in 27.7% of patients. Recurrence of calculi was observed during a median follow-up of 57 months in 4 patients with complete ultrasonographic clearance of the stone occurring 10 to 58 months after lithotripsy. A favorable treatment result was associated with younger age, parotid site of the stone, stone diameter less than or equal to 7 mm, and 6 or fewer therapeutic session.

Zenk et al. (2004) studied 197 patients with submandibular stones who were treated with ESWL from 1989 to 1994. The review analysis was completed in 2002. Thirty-five percent of the patients were either free of stones or had no symptoms from residual stones. Another 15% had a significant symptom improvement and needed no further therapy. The remaining 50% of patients had residual stones and no symptoms in the short review period, but have had symptoms since. Therapeutic success was influenced by stone location in the gland rather than stone size.

In a study of 122 salivary calculi treated by ESWL, Escudier (2003) reported complete success in 33% of patients. Thirty-five percent of patients were asymptomatic, although some stone debris remained in the duct. Failure occurred in 32% of the patients. The chance of failure increased with the size of the calculus and increasing symptom duration.
Nahlieli et al. (2010) assessed a combined external lithotripsy-sialoendoscopy method developed for advanced salivary gland sialolithiasis. A total of 94 patients (43 males and 51 females) underwent these treatment methods. Of these 94 patients, 60 had pathologic features in the submandibular gland and 34 in the parotid gland. A miniature external lithotripter was used, combined with multifunctional sialoendoscopes and endoscopic-assisted techniques, to achieve effective removal/elimination of the stones. Total elimination of the stone using lithotripsy alone was achieved in 32% of the cases; in 29%, intraductal endoscopic assistance was needed. In the remaining 39%, the removal of a stone was achieved with the help of an endoscopy-assisted extra-ductal approach (37 cases). At 6 months of follow-up, all patients who had undergone lithotripsy or lithotripsy plus intraductal endoscopy had an absence of symptoms. Of the 37 patients who had undergone an endoscopy-assisted extra-ductal approach, 35 (95%) remained asymptomatic. The investigators concluded that lithotripsy plus intraductal or extra-ductal endoscopic treatment of sialolithiasis is a highly effective surgical method of eliminating/removing salivary stones, especially those attached to the surrounding tissue and in the secondary ducts. This method helps to avoid resection of the salivary glands and represents an additional development of minimal invasive surgical techniques. This study is limited by lack of a control group and lack of long-term follow-up.

While the results of studies evaluating lithotripsy for treating salivary stones are promising, there is a need for additional research. Studies have thus far been small to moderate in size and uncontrolled.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has not approved the use of lithotriptors for the treatment of salivary stones. See the following Web site for information regarding FDA approved micro or miniature endoscopes for Ear, Nose and Throat (ENT) applications. Use product codes EOB and EOQ. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed May 2014.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for lithotripsy used in the treatment of salivary stones. Local Coverage Determinations (LCDs) do not exist at this time (Accessed June 25, 2014).

REFERENCES


**POLICY HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/2014</td>
<td>• Reorganized policy content</td>
</tr>
<tr>
<td></td>
<td>• Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:</td>
</tr>
<tr>
<td></td>
<td>o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)</td>
</tr>
<tr>
<td></td>
<td>o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBS; however, if such plans choose to</td>
</tr>
</tbody>
</table>
provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans
- The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage
  - Updated coverage rationale; added language to indicate the unproven services are “not medically necessary”
  - Updated supporting information to reflect the most current clinical evidence and references
  - Archived previous policy version 2013T0247J