

LITHOTRIPSY FOR SALIVARY STONES

Policy Number: 2018T0247P

Effective Date: December 1, 2018

[Instructions for Use](#) ⓘ

Table of Contents	Page
COVERAGE RATIONALE	1
APPLICABLE CODES	1
DESCRIPTION OF SERVICES	1
CLINICAL EVIDENCE	2
U.S. FOOD AND DRUG ADMINISTRATION	4
CENTERS FOR MEDICARE AND MEDICAID SERVICES	4
REFERENCES	4
POLICY HISTORY/REVISION INFORMATION	4
INSTRUCTIONS FOR USE	4

Related Commercial Policy

- [Extracorporeal Shock Wave Therapy \(ESWT\)](#)

Community Plan Policy

- [Lithotripsy for Salivary Stones](#)

COVERAGE RATIONALE

The following are unproven and not medically necessary for treating salivary stones due to insufficient evidence of efficacy:

- Extracorporeal shock wave lithotripsy (ESWL)
- Endoscopic intracorporeal laser lithotripsy

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies and Coverage Determination Guidelines may apply.

CPT Code	Description
42699	Unlisted procedure, salivary glands or ducts

CPT® is a registered trademark of the American Medical Association

DESCRIPTION OF SERVICES

Salivary glands secrete saliva into the mouth and throat aiding in digestion, moistening the mouth and protecting teeth from decay. The major salivary glands are the submandibular, sublingual and parotid glands. There are also minor salivary glands located in the lips, inner cheek area and extensively in other linings of the mouth and throat.

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 a 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, uses a pulsed dye laser to fragment the salivary stones from inside the body.

Koch et al. (2017) conducted a retrospective study in a tertiary referral center to assess results after treatment of difficult/complex sialolithiasis with extracorporeal shock-wave lithotripsy (ESWL) and intraductal pneumatic lithotripsy (IPL). Seventy-one ESWL procedures and 57 IPL were performed in our patients. Forty-nine stones were treated by 67 ESWL procedures and 52 IPL. ESWL converted sialoliths from sialendoscopically untreatable into sialendoscopically treatable cases in 94.7%; the treatment then was completed by a total of 52 IPL procedures. ESWL was performed before IPL (81.6%), in combination with IPL (7.9%) and after (10.5%). Complete fragmentation was achieved in 97.9%. Four stones each were treated with ESWL and IPL alone in multiple sialolithiasis. Altogether, 53 stones were treated by 57 IPL procedures. Complete fragmentation was achieved in 98.1% of the 53 stones. ESWL and IPL were the dominant treatment modalities in 84.1% of all 63 stones treated. Of all 38 patients, 92.1% became stone-free and all became symptom-free. All the glands were preserved. Multiple stones were treated in 34.2% of the patients; of these, 92.3% became stone-free. The authors concluded that patients with difficult and complex sialolithiasis can be treated with high success rates of > 90% using a multimodal, minimally invasive, and gland-preserving treatment approach. ESWL and IPL played a key role in this multimodal treatment regime in > 80% of stones. This study is limited by lack of a control group and small study population.

Capaccio et al. (2017) recent technological improvements in head and neck field have changed diagnostic and therapeutic strategies for salivary disorders, and extra- and intracorporeal lithotripsy, interventional sialendoscopy and sialendoscopy-assisted surgery are used as minimally invasive, conservative procedures for functional preservation of the affected salivary glands. The authors evaluated the results of a long-term experience in the management of paediatric obstructive salivary disorders. The study involved a consecutive series of 66 children whose obstructive salivary symptoms were caused by juvenile recurrent parotitis (JRP), stones, ranula and ductal stenosis. 45 patients underwent interventional sialendoscopy for JRP, stones and stenoses, with 12 receiving a cycle of extracorporeal shockwave lithotripsy (ESWL). Other procedures included: three sialendoscopy-assisted transoral surgeries, one drainage, six marsupializations, and two suturing of a ranula. Three children underwent combined ESWL and interventional sialendoscopy, and seven a secondary procedure. Three children underwent combined ESWL and interventional sialendoscopy. An overall successful result was obtained in 90.9% of cases. None of the patients underwent traditional invasive sialadenectomy notwithstanding persistence of mild obstructive symptoms in six patients. No major complications were observed. Using a diagnostic work-up based on colour Doppler ultrasound, Magnetic Resonance sialography and cone beam 3D TC, children with obstructive salivary disorders can be effectively treated in a modern minimally-invasive manner by extracorporeal and intracorporeal lithotripsy, interventional sialendoscopy and sialendoscopy-assisted transoral surgery; this approach guarantees a successful result in most patients, thus avoiding the need for invasive sialadenectomy while functionally preserving the gland. This study is limited by the small number of the children receiving ESWL.

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 MINLITH 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 98%, 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 of extracorporeal shock wave lithotripsy of salivary stones, 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.

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 approved several lithotripter devices. See the following website for information and approved indications [use product code FFK or GEX (for laser powered devices)]:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed June 15, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for extracorporeal shock wave lithotripsy (ESWL) or endoscopic intracorporeal laser lithotripsy used in the treatment of salivary stones. Local Coverage Determinations (LCDs) do not exist at this time.

(Accessed June 15, 2018)

REFERENCES

- Capaccio P, Canzi P, Gaffuri M, et al. Modern management of paediatric obstructive salivary disorders: long-term clinical experience. *Acta Otorhinolaryngol Ital*. 2017 Apr; 37(2):160-167.
- Desmots F, Chossegras C, Salles F, et al. Lithotripsy for salivary stones with prospective US assessment on our first 25 consecutive patients. *J Craniomaxillofac Surg*. 2013 Sep 5. pii: S1010-5182(13)00227-8.
- Escudier MP, Brown JE, Putcha V, et al. Factors influencing the outcome of extracorporeal shock wave lithotripsy in the management of salivary calculi. *Laryngoscope*. 2010 Aug;120(8):1545-9.
- Hayes, Inc. Directory. Sialoendoscopy for Salivary Gland Stones. August 2014. Updated July 16, 2015. Archived October 26, 2017.
- Iro H, Zenk J, Escudier MP, et al. Outcome of minimally invasive management of salivary calculi in 4,691 patients. *Laryngoscope*. 2009 Feb;119(2):263-8.
- Koch M, Schapher M, Mantsopoulos K, et al. Multimodal treatment in difficult sialolithiasis: Role of extracorporeal shock-wave lithotripsy and intraductal pneumatic lithotripsy. *Laryngoscope*. 2017 Dec 15.
- Nahlieli O, Shacham R, Zaguri A. Combined external lithotripsy and endoscopic techniques for advanced sialolithiasis cases. *J Oral Maxillofac Surg*. 2010 Feb;68(2):347-53.
- Phillips J, Withrow K. Outcomes of Holmium Laser-Assisted Lithotripsy with Sialendoscopy in Treatment of Sialolithiasis. *Otolaryngol Head Neck Surg*. 2014 Mar 5.
- Schmitz S, Zengel P, Alvir I, et al. Long-term evaluation of extracorporeal shock wave lithotripsy in the treatment of salivary stones. *J Laryngol Otol*. 2008 Jan;122(1):65-71.
- Zenk J, Koch M, Klintworth N, et al. Sialendoscopy in the diagnosis and treatment of sialolithiasis: a study on more than 1000 patients. *Otolaryngol Head Neck Surg*. 2012 Nov;147(5):858-63.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	<ul style="list-style-type: none">Reorganized policy template:<ul style="list-style-type: none">Simplified and relocated <i>Instructions for Use</i>Removed <i>Benefit Considerations</i> sectionSimplified coverage rationale (no change to guidelines)Archived previous policy version 2018T02470

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right 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. UnitedHealthcare Medical Policies 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.