Lithotripsy for Salivary Stones (for Tennessee Only)

Policy Number: CS070TN.M
Effective Date: January 1, 2025

➲ Instructions for Use

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Related Policy

- Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds (for Tennessee Only)

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

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

- 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 federal, state, or contractual requirements 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 Guidelines may apply.

CPT Code	Description
42699	Unlisted procedure, salivary glands or ducts

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Description of Services

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. Minimally invasive gland-preserving 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 lithotripsy uses a lithotripsy probe inserted into the salivary duct under endoscopic guidance, and directly reaches the stone's surface and introduces shock waves in the form of laser beams, pneumatic devices, and electro-hydraulic or electrokinetic probes. The goal of both techniques is to reduce the size of the sialoliths making them more easily cleared from the salivary duct system spontaneously after sialogogue-induced salivation, or during endoscopic procedures.

Clinical Evidence

There is insufficient quality evidence to support the use of extracorporeal shock wave and endoscopic intracorporeal laser lithotripsy for managing salivary stones. Available evidence consists primarily of single-arm studies, a design generally considered of very low quality in hierarchies of evidence. A limited number of controlled studies are reported that do not clearly support the benefit of lithotripsy and are limited by lack of randomization, masking, or adjustment for confounding factors. Further research with well-designed and preferably randomized controlled studies with larger patient sample sizes is required to demonstrate safety and efficacy.

Koch et al. (2022) conducted a retrospective study to report the results of using a pneumatic lithotripter for the treatment of salivary stones. Seventy-seven salivary stones (43 in the submandibular gland (SMG) and 34 in the parotid gland [PG]) in 62 patients were treated. A significant number of patients had difficult locations of stones. The results showed complete fragmentation was achieved in 76 of 77 stones and the fragments of 74 were extracted completely. In the 3 cases that complete extraction was not achieved, 1 or 2 small residual fragments (1-4 mm) were washed too far proximally into the intraparenchymal duct system. All patients became symptom free. No differences between the different glands were observed. As has been found in other studies, various levels of damage of the duct epithelium happen after ISWL in nearly all cases. This is caused by impaction of the stone and/or by the procedure itself. Complications were infrequent with no differences between the SMG and PG or stone size in either gland. Multimodal therapy (including ESWL, interventional endoscopy, laser lithotripsy) was performed in 13 cases. Twenty-two patients were treated after or in combination with transoral duct surgery. This study is limited by the lack of a control group and small number of participants.

In a 2021 systematic review, Chiesa-Estomba et al. analyzed the current literature on the role of laser assisted lithotripsy with sialendoscopy (LAS) in the treatment of major salivary gland lithiasis and provide an evidence-based perspective on clinical outcomes. Study selection criteria were as follows: reported the results for at least 10 adult patients treated for obstructive salivary gland disease via LAS, describe the type of laser device used, gland affected, stone size, outcome and complications as well as success with salivary gland preservation. The primary outcome evaluated was symptom resolution (a secondary outcome was salivary gland preservations) in a 3 month follow up timeframe. There were 16 studies that met all the inclusion criteria, 11 were clinical retrospective nonrandomized uncontrolled studies, and 5 prospective nonrandomized studies. The most reported glands were the submandibular and parotid. Results showed a success rate for stones with a mean maximum diameter of 7.11 mm ranging from 71%-100% with a gland preservation rate of 97%. The authors concluded that this systematic review suggests LAS can be an efficient, safe and gland preserving technique when done by experienced hands for the management of midsize sialolith removal from major salivary glands. However, due to the low evidence level (mostly case series without a comparison group), additional prospective-randomized trials are needed to determine the definitive role of this technique in the management of obstructive salivary gland disorders and make stronger and more precise recommendations for use of laser technology for management of not only larger stones but also other obstructive pathology such ductal stenosis.

Guenzel et al. (2019, included in the Chiesa-Estomba review above) conducted a retrospective, interventional consecutive case series to evaluate the safety and efficiency of holmium laser-assisted lithotripsy during sialendoscopy of the submandibular gland. A total of 374 consecutive submandibular gland sialendoscopy procedures were performed in 276 patients with sialolithiasis from 2008 to 2015. Holmium laser-assisted Laser lithotripsy was performed in 109 cases (64.9%). Smaller mobile concrement was removed directly either by forceps or wire basket or following marsupialization of the submandibular duct. This was the case in 88 patients (29.1%). Three patients (0.8%) required surgical removal of the submandibular gland due to early abscess. Most patients (n = 374 procedures; 90.1%) remained symptom-free after two or more years following intervention. In the remaining procedures (n = 37 procedures; 9.9%), patients reported discreet postprandial problems but did not seek medical attention. The authors concluded that Holmium laser-assisted lithotripsy is a simple, safe, and effective procedure for treating patients with sialolithiasis of the submandibular gland. This study is limited by a lack of a comparator group. Further investigation with prospective randomized controlled studies is needed to determine the effectiveness of laser-assisted lithotripsy in the treatment of salivary stones.

Koch et al. (2017) conducted a retrospective case series 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 their 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.

In Capaccio et al. (2017), the authors evaluated the results of a long-term experience in the management of pediatric 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. According to the authors, using a diagnostic work-up based on color 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; the state that 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, observational design, and lack of adjustment for confounding factors.

Phillips and Withrow (2014, included in the Chiesa-Estomba review above) 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 in a cohort study. 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 however non-randomized 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 comparison with a control group. There was no diagnostic reference standard so a comparison between different removal methods was not possible.

In a prospective case series, 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 dependent mainly on size of the stone. This study is limited by lack of comparison group or long-term follow-up.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved several lithotripter devices. Refer to the following website for information and approved indications using product code FFK or GEX for laser powered devices: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 15, 2024)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS070TN.L

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. 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.

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