Sialolithiasis (Salivary Stones)

Number: 0716

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers sialendoscopy (diagnostic or therapeutic) medically necessary for the management of chronic sialadenitis and sialolithiasis.
Aetna considers the following experimental and investigational because their effectiveness has not been established:

- Alpha-blockers for the treatment of sialolithiasis
- Contrast-enhanced ultrasound for the management of sialolithiasis
- Elastography for the evaluation of sialolithiasis
- Endoscopic intracorporeal laser lithotripsy for the treatment of sialolithiasis
- Endoscopic pneumatic lithotripsy for the treatment of sialolithiasis
- Extracorporeal shock wave lithotripsy for the treatment of sialolithiasis
- Sialodochoplasty for the treatment of submandibular sialolithiasis

Background
Sialolithiasis refers to non-cancerous stones (calcium-rich crystallized minerals known as salivary calculi or sialoliths) in a salivary gland or duct. Most salivary stones are single; however multiple stones may be present. There are three pairs of major salivary glands: (i) the parotid glands, (ii) the sublingual glands, and (iii) the submandibular glands. In addition to these major glands, there are hundreds of minor salivary glands that are scattered throughout the mouth and throat. The submandibular glands are most often affected by stones (about 80% of cases), followed by the parotid gland and duct. Stones are rarely found in the sublingual gland. The higher frequency of sialolithiasis in the submandibular gland is associated with several factors: the pH of saliva (alkaline in the submandibular gland, acidic in the parotid gland); the viscosity of saliva (more
mucous in the submandibular gland); and the anatomy of the Wharton’s duct (the duct of the submandibular salivary gland opening into the mouth at the side of the frenum linguae is an “uphill course”).

Although the exact cause of sialolithiasis remains unclear, some salivary stones may be related to dehydration, which increases the viscosity of the saliva; reduced food intake, which decreases the demand for saliva; or medications that lower the production of saliva, including certain anti-histamines, anti-hypertensives and anti-psychotics. Some salivary stones may not produce any symptoms. In other cases, a stone may partially or completely block the gland or its duct causing pain and swelling in the affected gland/duct, especially when eating. While small salivary stones sometimes pass out of the duct on their own, larger stones usually remain in the gland until they are removed. In general, stones within the distal salivary duct are easily removed by trans-oral ductotomy. On the other hand, proximal stones are usually treated by excision of the salivary gland and its duct. Another relatively new therapeutic option for the treatment of sialolithiasis is extracorporeal shock wave lithotripsy (ESWL), which utilizes ultrasound to break up the stones. The broken fragments can then pass out along the duct. Although there is some preliminary evidence that ESWL may be of clinical value in treating patients with salivary stones, its effectiveness has not been validated by prospective randomized controlled studies.

In an experimental study, Escudier and associates (2003) examined the results of ESWL in the management of salivary stones (38 parotid and 84 submandibular). Complete success was achieved in 40 procedures (33 %), 27 of 84 (32 %) submandibular and 13 of 38 (34 %) parotid calculi. A further 43 patients (35 %) were rendered asymptomatic although some stone debris remained in the duct (26 submandibular and 17 parotid). Failure (retention of stone debris and continued symptoms) occurred in 39 patients (32 %), 30 submandibular and 8 parotid glands. The chance of failure increased with the size of the calculus and increasing duration of symptoms. These
researchers reported that ESWL provides a useful option for the management of salivary stones, especially those that are less than 7 mm in diameter.

In a consecutive patient series, Capaccio et al (2004) evaluated the validity of ESWL for the treatment of sialolithiasis in a large series of patients with a long-term follow-up (median period of 57 months). A total of 322 symptomatic outpatients with solitary or multiple calculi in the submandibular (234 patients) or parotid (88 patients) gland underwent a complete ESWL treatment. Results were classified into 3 groups: (i) successful result with complete ultrasonographic elimination of the stone after lithotripsy, (ii) successful result with residual ultrasonographic fragments that were less than 2 mm in diameter, and (iii) unsuccessful result with residual ultrasonographic fragments that were greater than 2 mm in diameter. Complete elimination of the stone was achieved in 45 % of patients. On ultrasonography, residual fragments (less than 2 mm in diameter) were detected in 27.3 % of patients, and persisting fragments greater than 2 mm in diameter were found in 27.7 % of patients. In 3.1 % of patients, all with submandibular gland stones, sialoadenectomy was performed. Recurrence of calculi in the treated gland was observed during a median follow-up period of 57 months in 4 patients with complete ultrasonographic clearance of the stone occurring 10 to 58 months after lithotripsy. On multivariate analysis, the age of the patient, parotid site of the stone, stone diameter, number of therapeutic sessions, and number of shock waves were associated with favorable outcome. These investigators concluded that this minimally invasive approach should be considered an efficient therapy for salivary calculi.

The results by Escudier and colleagues (2003) as well as Capaccio et al (2004) were unimpressive. Complete success (elimination of stones) was achieved in only 33 % of patients in the former study and 45 % of patients in the latter study.

Zenk and colleagues (2004) performed a retrospective review on effectiveness of ESWL in the treatment of submandibular
stones (n = 191). The period under review ranged from 8 to 13 years, with an average of 10.5 years. In all, 35% of the subjects (n = 67) were either stone-free or asymptomatic from the residual stones. Another 15% (n = 29) had a significant improvement in their symptoms and needed no additional treatment. The remaining 50% (n = 95) had residual stones; they had no symptoms in the short review period, but have had symptoms since. The therapeutic success was not influenced by the size of the stone (this appears to be contradictory to the findings of Escudier et al, 2003), but by its location within the gland. Following treatment, no severe adverse events were identified. The authors concluded that ESWL is a possible therapy for submandibular stones and when combined with other gland-preserving methods forms part of a multi-therapeutic approach that renders submandibulectomy unnecessary in the majority of cases.

Yoskovich (2003) stated that in patients with stones in proximity of the opening of the Wharton’s duct, the duct can be cannulated, dilated and the stones removed through a trans-oral approach. The author also stated that for patients with deep intra-parenchymal stones or multiple stones, the glands should be excised; ultrasonic lithotripsy is rarely effective.

In a review on the management of salivary stones, Marchal and Dukguerov (2003) commented that, with external lithotripsy, stones are expected to evacuate spontaneously once fragmented. Although success rates of 75% for the parotid gland and 40% for the submandibular gland have been reported with ESWL, any residual stone is an ideal nidus (a point or place at which something originates, accumulates, or develops, as the center around which salts of calcium, uric acid, or bile acid form calculi) for further calcification and recurrence of salivary stones. These investigators also noted that external lithotripsy could cause significant damage to the salivary glands. Moreover, in a review on management modalities of submandibular sialoliths, Baurmash (2004) stated that lithotripsy does not appear to be a viable routine method of
management for submandibular salivary stones.

McGurk et al (2005) examined the results of a minimally invasive approach in the treatment of salivary calculi (323 submandibular stones and 132 parotid stones). Patients were treated using ESWL, fluoroscopically guided basket retrieval or intra-oral stone removal under general anesthesia. The techniques were used either alone or in combination. Exclusion criteria for ESWL include pregnancy, stones not readily identifiable by ultrasonography, patients with blood dyscrasias or hemostatic abnormalities, and individuals who have undergone stapedectomy or ossicular repair. Extracorporeal shock wave lithotripsy resulted in complete success (stone-free and symptom-free) in 87 (39.4 %) of 221 patients [84 (38.5 %) of 218 primary and all of 3 secondary procedures; 43 (32.8 %) of 131 submandibular, 44 (48.9 %) of 90 parotid]. Basket retrieval cured 124 (74.7 %) of 166 patients (103 of 136 primary and 21 of 30 secondary procedures; 80 of 109 submandibular, 44 of 57 parotid). Intra-oral surgical removal was successful in a further 137 (95.8 %) of 143 patients with submandibular stones (99 of 101 primary, 36 of 38 secondary and 2 of 4 tertiary procedures). The overall success rate for the three techniques was 348 (76.5 %) of 455. It should be noted that the ESWL achieved complete success only in 39.4 % of patients. The authors also noted that earlier studies reported presence of residual fragments in 54 to 67 % of patients who had undergone ESWL for salivary calculi. These investigators claimed that minimally invasive techniques such as ESWL for the management of patients with sialolithiasis are still at an early stage of development.

Schmitz and colleagues (2008) retrospectively assessed the results of the ESWL in 167 outpatients with symptomatic stones (average size of 5.94 mm) of the salivary glands over a 7-year period. A successful treatment with total stone disintegration was attained in 51 (31 %) patients. In 92 (55 %) patients, treatment was partially successful with disappearance of the symptoms but a sonographically still identifiable stone. Treatment failure occurred in 24 (14 %) patients who then
underwent surgery. The mean follow-up period was 35.6 months (minimum of 3, maximum of 83), after which 83.2 % of the initially successfully treated patients were still symptoms-free.

While the results of recent reports are encouraging, further investigation (especially prospective randomized controlled studies) is needed to ascertain the effectiveness of extracorporeal shock wave lithotripsy in the treatment of salivary stones.

Sialoendoscopy (salivary gland endoscopy) is an image-guided technique for the evaluation and treatment of patients with obstructive disease of the parotid salivary glands. Obstruction of the ducts is most commonly caused by sialolithiasis. Nahlieli and Baruchin (1999) described the use of endoscopy for diagnostic and surgical intervention in the major salivary glands of patients who have obstructive pathology. A total of 154 salivary glands (96 submandibular glands, 57 parotid glands, 1 sublingual gland) suspected of having obstructive pathology (89 males, 65 females; aged 5 to 72 years) were treated using a mini-endoscope. Most procedures were performed under local anesthesia in an outpatient clinic. All patients underwent pre-operative and post-operative screening by routine radiography, sialography, and ultrasound. The indications for endoscopy were: (i) calculus removal that could not be performed by conventional methods, (ii) screening of the salivary ductal system for residual calculi after sialolithotomy, (iii) positive evidence of ductal dilatation or stenosis on the sialogram or ultrasound examination, and (iv) recurrent episodes of major salivary gland swellings without known cause. Of the 154 endoscopies performed, 9 were immediate failures as a result of technical problems. Of the remaining 145 glands, 112 had obstructions and 33 had sialadenitis alone. The success rate was 82 % for calculus removal. Before sialoendoscopy, 32 % of the submandibular and 63 % of the parotid sialoliths, and the 1 stone in the Bartholin's duct, were undetected. Multiple endoscopic findings were encountered. No major complications were noted. The authors concluded
that sialoendoscopy is a minimal invasive technique for the
diagnosis and removal of obstructive pathologic tissue in the
major salivary glands. Nahlieli and colleagues (2006) also
reported that their overall success rate for parotid endoscopic
sialolithotomy was 86%; the overall success rate for
submandibular endoscopic sialolithotomy was 89%; and the
success rate for treating strictures was 81%.

Baptista et al (2008) reported their experience on the use of
sialoendoscopy for the treatment of salivary pathology. Of the
8 patients who underwent sialoendoscopy, 4 were diagnosed as
having sialolithiasis and the remaining 4 had chronic
sialoadenitis. In patients with sialolithiasis, sialoendoscopy
allowed the extraction of the calculus in 2 patients (50%). For
the remaining subjects, sialoendoscopy provided confirmation
of the diagnosis in all cases. The authors concluded that
sialoendoscopy can be used for the diagnosis, treatment and
post-operative management of sialolithiasis, sialoadenitis and
other salivary gland pathologies.

Yu et al (2008) described the cause, exploration, and combined
management of chronic obstructive parotitis by means of
sialoendoscopy. A total of 23 patients with obstructive
symptoms were diagnosed by sialography and explored by
diagnostic sialoendoscopy. The obstructions were removed by
interventional sialoendoscopy. After obstructions were
removed successfully, 0.25% chloramphenicol was used to
lavage the duct continuously, and then 40% iodized oil was
perfused into duct. The results of follow-up were evaluated by
visual analog scales (VAS) of the clinical appearances at
different stages. Twenty of the 23 patients were found with
various types of stenosis and dilatation of duct on sialography,
and 21 patients were explored using sialoendoscopy
successfully. The features of these 21 cases found
endoscopically were of 4 types: sialolith (n = 4; 19.0%), duct
polyps (n = 5; 23.8%), stenosis (n = 3; 14.3%), and mucus plug
(n = 9; 42.9%). Seventeen cases were treated successfully,
removing obstructions via sialoendoscopy, giving a success rate
of 80.9% (17 out of 21). The satisfactory rate after 6 months
was 82.4 % by VAS and secretion observation.

Papadaki et al (2008) described their early clinical experience with endoscopic salivary duct exploration and sialolithectomy in 2 medical centers. This was a retrospective case series of 94 patients, with submandibular (n = 77) or parotid (n = 17) sialadenitis secondary to sialolithiasis, strictures, or mucous plugs. Patients underwent sialoendoscopy at the Baptist Hospital, Miami (n = 52) or at the Massachusetts General Hospital, Boston (n = 42). Dilatation of the duct through the natural orifice was carried out with salivary dilators. Three endoscope systems with diameters from 1.1 to 2.3 mm were used. Using a basket, grasper, lithotripsy, laser, or a combination of these, stones were fragmented or removed endoscopically. Strictures were dilated and mucous plugs removed. All cases were carried out under general anesthesia. Salivary duct navigation was accomplished in 91/94 patients. In 3 cases, duct dilatation was not possible due to scarring. Symptomatic relief was achieved in 81/91 patients (89.4 %). Strictures and mucous plugs were visualized and managed in 18/18 patients. Sialoliths were visualized in 73 patients and stone fragmentation or retrieval was accomplished in 62 of 73 (84.93 %) cases. Complications included 2 patients with temporary lingual nerve paresthesia and 1 patient with excess extravasation of irrigation fluid. The authors concluded that the findings of this study indicated that interventional sialoendoscopy is an effective, minimally invasive alternative treatment for obstructive salivary gland disease.

Faure and co-workers (2008) stated that sialendoscopy is finding increasing application in the management of salivary-gland swellings as it provides a diagnostic method for the main salivary ducts coupled with a therapeutic tool. Many studies have emphasized the diagnostic and therapeutic advantages of this non-invasive technique. Furthermore, new semi-rigid sialendoscopes and complete miniaturized instrumentation allow diagnosis and treatment of obstructive pediatric salivary-gland swelling. Pediatric sialendoscopy has allowed clinicians to recognize salivary stones and stenoses.
mis-diagnosed by conventional radiography or ultrasound. Pediatric sialendoscopy is now an improved diagnostic technique for obstructive salivary-gland swelling. It has a greater sensitivity than conventional radiology ultrasound and MRI.

Faure et al (2007) evaluated the effectiveness of sialendoscopy as a diagnostic and interventional procedure for salivary ductal pathologies in children. A total of 8 children were examined under general anesthesia by sialendoscopy for recurring salivary gland swellings. Diagnostic sialendoscopy was used for classifying ductal lesions as sialolithiasis or stenosis. Intervventional sialendoscopy was used to treat these disorders. Different variables were analyzed: type of endoscope used, intra-operative findings, type of device used for sialoliths fragmentation or extraction, total number of procedures, as well as size and number of sialoliths removed. Five cases of parotid and 3 cases of submandibular gland recurring swellings were included in the present study. Diagnostic sialendoscopy was possible in all cases. Salivary stones were found in 6 patients and parotid ductal stenosis in the remaining 2. Multiple stones were seen in 2 cases. Intervential sialendoscopy was also possible in all cases, allowing an intra-ductal retrieval of the stones in 3 cases, and a marsupialization of the duct in 2 cases. Two cases required laser fragmentation of the stone. No major complications occurred intra-operatively or during follow-up (mean of 18 months). The authors concluded that diagnostic sialendoscopy is a new technique allowing a reliable evaluation of salivary ductal disorders in children, with low morbidity. Interventional sialendoscopy allows early treatment of pediatric sialoliths and stenosis in most cases, avoiding classical open surgery.

In a prospective case series study, Quenin et al (2008) evaluated the relevance of sialendoscopy as a diagnostic and interventional procedure in juvenile recurrent parotitis (JRP). Sialendoscopy was used to examine 10 children (aged 1.8 to 13.0 years) with symptomatic JRP for recurrent swelling of the parotid glands. Diagnostic sialendoscopy allowed classification
of ductal lesions, and interventional sialendoscopy was used to treat the lesions. Initial data analyzed included the type of endoscope used as well as the size and form of the main duct of the parotid gland. Outcome variables were resolution of symptoms and endoscopic enlargement of the ductal tree. Initial ultrasound evaluation of the diseased gland revealed a white Stensen duct without the natural proliferation of blood vessels in all 10 cases. This finding was associated with a true stenosis of the Stensen duct. Two cases of suspected stones according to ultrasonography were subsequently diagnosed as localized stenoses. The sialendoscope was used to dilate the duct with pressurized saline solution in all cases as well as to dilate the 2 cases of stenoses. There were no major complications. The average length of follow-up was 11 months (range of 2 to 24 months). Seventeen parotid glands were dilated in all 10 patients, with a success rate of 89%. One patient needed repeated sialendoscopies for recurrent symptoms. Two patients presented with a second episode of JRP contralateral to the side initially treated. The authors concluded that diagnostic sialendoscopy is a new procedure that can be used in children for reliable evaluation of salivary ductal disorders, with low morbidity. Sialendoscopic dilation of the main parotid ducts appears to be a safe and effective method for treating JRP.

The National Institute for Health and Clinical Excellence's guidance on therapeutic sialendoscopy (NICE, 2007) stated that current evidence on the safety and effectiveness of this technology appears adequate to support the use of this procedure. The Specialist Advisers did not consider there to be any uncertainties about this procedure. One Advisor noted that high success rates are reported in the published literature.

In a retrospective study, Guerre and associates (2010) evaluated the safety and effectiveness of alfuzosin, an alpha-blocker, in patients with ductal stenosis, allergic pseudo-parotitis or sialolithiasis after lithotripsy. A total of 352 patients were included; 194 of whom presented with sialolithiasis fragmented by extracorporeal lithotripsy (112 parotidic and 82
submandibular); 69 presented with ductal stenosis, and 89 with allergic pseudo-parotitis. This study lasted 3 years with a mean follow-up of 33 months (18 months to 4 years). Male patients were given 2.5 mg thrice-daily of alfuzosin and female patients 2.5 mg twice-daily for 3 to 24 months. After 6 months and up to 2 years of treatment, patients were assessed every 3 months by ultrasound and with a questionnaire on symptoms. Results were similar in male and female patients -- 80% of patients with colic-like pain due to stenosis reported a significant improvement after treatment; 78.6% of patients with allergic pseudo-parotitis felt they had improved and noted a sharp decrease of pruritis; 67 of the patients with residual parotid lithiasis after extracorporeal lithotripsy presented with less ductal lithiasis and fragments were evacuated more rapidly in the 2 months following lithotripsy; 42% of the patients treated for residual submandibular lithiasis reported a significant functional improvement and faster evacuation of fragments. The drug was well-tolerated; 12 out of 352 patients (3.4%) reported adverse effects and the incidence of orthostatic hypotension was 2.2%. The authors concluded that a significant improvement of symptoms was observed in patients treated with alfuzosin for obstructive salivary gland diseases. They stated that these preliminary results should be confirmed with a prospective controlled study.

Maresh et al (2011) stated that sialoendoscopy is a new technology being used at a limited number of institutions for the diagnosis and management of obstructive sialadenitis. This technique is promising for its superior diagnostic potential as well as its decreased morbidity compared to traditional more invasive techniques for managing obstruction. The authors reviewed the sialoendoscopy experience at their institution to identify successes, areas of improvement, and to provide guidance to other programs that may be interested in sialoendoscopy. These investigators did a retrospective review of all diagnostic and interventional sialoendoscopies performed at this institution from 2007 to 2009. Charts were reviewed for epidemiologic and clinical data, as well as procedural techniques, findings, and outcomes. They attempted 37 parotid
and submandibular sialoendoscopies, with successful endoscopic canalization of the duct in 36 of these cases. Twenty of 25 stones were removed from 18 patients. Stones that were larger than 5 mm were more difficult to dislodge and remove without fragmentation. Other abnormal findings included strictures, scars, and mucoid debris. There were 2 failures of technique, and 2 patients had post-operative purulent sialadenitis that resolved after antibiotics. The authors concluded that as an institution that recently began performing sialoendoscopies, they showed similar success rates compared to other programs. Obstacles included the initial cost of acquiring equipment and the associated learning curve of using a new technique. Similar to other programs, successful extraction of sialoliths was limited with larger stones.

Kopec and colleagues (2011) stated that approximately 5 % of patients visit the ENT doctors with major salivary gland complaints. Chronic sialadenitis is one of the major disorders that can cause salivary hypofunction and correct diagnosis and management is essential for its recovery. The classification of this pathological condition have changed in the past 8 decades and nowadays was revised and modified, for new diagnostic (high resolution ultrasonography, CT and MR sialography and sonoelastography) and therapeutic methods (sialoendoscopy) were introduced. These researchers revived the past classifications of chronic inflammatory diseases of the major salivary glands and present the current one with implications for diagnostic and treatment schedule. A total of 20 patients with parotid and 44 with submandibular gland sialadenitis were treated in the years 2007 to 2010. Two periods of time: 2007 to 2008 and 2009 to 2010 were compared, the turn-point was December 2008, when sialoendoscopy was introduced. 25 out of 50 patients with parotid and 73 out of 95 with submandibular sialadenitis suffered from lithiasis. Surgical evacuation of the stone was performed in 10 cases in 2007 to 2008, and in 4 between 2009 and 2010. In this last period, a total of 94 sialoendoscopies were performed, in this number in case 38 submandibular and 7 parotid lithiasis. Stensens duct stenosis was diagnosed in 7 and Wharton duct in 12 patients.
The authors concluded that prompt diagnosis is indispensible for the proper, further treatment. They recommended treatment of chronic and obstructive sialadenitis with sialoendoscopy.

Furthermore, an UpToDate review on “Salivary gland stones” (Fazio and Emerick, 2012) states that “In a systematic review, the overall success rate of sialoendoscopy (for a variety of indications, including obstructive stones, stenosis, and sialadenitis) was 86 percent”.

Zengel and colleagues (2012) noted that obstructive diseases of the salivary glands are often based on sialolithiasis, but can also result from rare circumstances. Due to recent technical innovations, there has been significant development in the treatment of obstructive diseases of the salivary glands such that minimally invasive glandula-sustaining therapy has now become standard. However, there is still no effective technique to assess and monitor the recovery of the parenchyma of the gland. As a result, recurrent infections often lead to modification of the gland in which fibrosis increases and the gland becomes coarse. After treatment, the parenchyma of the gland is able to recover. Thus, to more effectively monitor and promote the success of treatment, these researchers developed a new method to measure and quantify the stiffness of the glandula tissue using elastography (Virtual Touch TM Application) to assess the degree of recovery. First, they collected elastography data from 30 healthy volunteers as part of a conventional ultrasound (Siemens, ACUSON, S 2000, Germany) with a multi-frequency linear 9-MHz transducer in order to determine if normal findings are sufficiently quantifiable. They subsequently measured patients with sialolithiasis of the submandibular gland. For healthy volunteers, the average value was 1.96 +/- 0.48 m/s for the glandula submandibularis and 2.66 +/- 0.89 for the parotid gland, a statistically significant difference. For patients with sialolithiasis of the submandibular gland, the average value was 2.98 +/- 0.4 m/s, a highly significant difference in comparison to the healthy side of the patient. The authors concluded that
elastography is an easy to use diagnostic method that shows promise to become a valuable tool for the assessment of disease severity as it provides the possibility to quantify the level of treatment benefit for the patient.

In a prospective clinical evidence level 2c study, Siedek et al (2012) evaluated contrast-enhanced ultrasound (CE-US) as a quantitative monitoring technique during gland-preserving ESWL. Perfusion in patients (n = 10) with unilateral sialolithiasis of the submandibular gland was quantitatively analyzed using CE-US before and after ESWL, comparing with the respective contralateral gland. Before CE-US measurements, a subjective clinical score of complaints (range of 1 to 10) was documented. The contrast agent SonoVue was injected into a cubital vein. The intensity-time curve gradients (ITGs) were calculated from CE-US data. The ITGs derived from CE-US measurements revealed higher perfusion in the affected submandibular gland compared to the contralateral side. In parallel to clinical complaints, parametric CE-US data were significantly reduced after ESWL in chronic sialolithiasis-associated sialadenitis. The authors concluded that CE-US-derived ITGs appear to be an independent and quantitative marker for treatment effects of ESWL. They stated that clinical experience and further studies will have to validate this method as a diagnostic tool to decide especially whether to proceed to sialoadenectomy in therapy-refractory cases.

Strieth et al (2014) evaluated feasibility to distinguish different entities of submandibular gland disease including inflammatory alterations of the submandibular gland as well as benign and malignant tumors. In this prospective clinical study, intensity-time gradients (ITGs) in 30 patients with sialolithiasis-related chronic sialadenitis or an unilateral submandibular mass and 18 disease-free submandibular gland controls were quantitatively analyzed by contrast-enhanced ultrasound (CEUS) using the contrast agent SonoVue. In addition, clinical complaints according to VAS were documented; VAS data documented significantly less complaints only in benign tumors compared with the other pathologies of the submandibular
gland. In parallel, CEUS-derived ITGs revealed significantly reduced ITGs only in benign tumors (n = 5) compared to the controls (n = 18). Despite of comparably reduced wash-in velocities in malignant lesions (n = 3) statistical significance was not reached. Chronic sialadenitis (n = 18) and its sclerosing variant (Kuttner tumor, n = 4) revealed comparable ITGs as controls. Tumors of the submandibular gland present with reduced functional microcirculatory networks comparing with healthy gland controls and chronically inflamed submandibular glands. Thus, dynamic CEUS-derived ITGs in combination with conventional clinical measures (e.g., VAS) appear as a safe and promising strategy for non-invasive diagnostic work-up of submandibular lesions; and warrant further validation in a larger set of patients.

Park and colleagues (2012) stated that the transoral removal of stones by sialodochoplasty has been popularized in the treatment of submandibular sialolithiasis. However, the effectiveness of sialodochoplasty is controversial, and there are no reports on the long-term outcomes of this procedure. These investigators evaluated the effectiveness and long-term outcomes of sialodochoplasty in patients with submandibular sialolithiasis. They conducted a cross-sectional study that included retrospective chart reviews and prospective telephone or interview surveys of 150 patients treated for submandibular sialolithiasis from March 2001 to January 2008. These patients were treated with 2 different procedures by 2 different surgeons. One surgeon performed a transoral sialolithectomy without sialodochoplasty in 107 patients (SS group), and the other surgeon performed a transoral sialolithectomy with sialodochoplasty in 43 patients (SP group). The success rate of transoral sialolithectomy was 98.1 % in the SS group and 93 % in the SP group. The recurrence rates of symptoms or stones were 1.9 % and 4.7 % in the SS and SP groups, respectively. The incidence of post-operative transient hypoesthesia was 13.1 % in the SS group and 34.9 % in the SP group. The mean operating times were 29.79 and 47.44 minus in the SS and SP groups, respectively. The mean percentage of general anesthesia was 42.1 % in the SS group and 83.7 % in the SP.
group. The authors concluded that sialodochoplasty in addition to transoral sialolithectomy for submandibular sialolithiasis did not affect the rate of symptom or stone recurrence, but did increase the post-operative hypoesthesia incidence and general anesthesia percentage.

In a case-series study, Martellucc et al (2013) evaluated the feasibility of intracorporeal lithotripsy with holmium:YAG laser under sialoendoscopic guidance for sialolithiasis of Wharton's duct. This study was conducted on 16 patients with sialolithiasis of Wharton's duct. Diagnosis was confirmed at ultrasound examination. Patients with stones ranging from 5 to 8 mm in diameter were enrolled in the study. The selected patients underwent intracorporeal lithotripsy with holmium:YAG laser under endoscopic control. Debris was removed using sialoendoscopic forceps or a wire basket during the same procedure. After a 3-month follow-up, radiological tests were re-run. Stone fragmentation was possible in all cases. All patients experienced a regular post-operative course. Post-operative ultrasound examinations revealed residual stones in 3 patients, 1 of whom was asymptomatic. Three patients complained of residual symptoms after 3 months of follow-up. These patients were treated successfully during a 2nd sialoendoscopic procedure. The authors concluded that in their experience, endoscopic laser lithotripsy was proved to be a feasible technique for Wharton's duct lithiasis in clinical practice. This was a feasibility study; the clinical effectiveness of endoscopic intracorporeal laser lithotripsy awaits results of well-designed studies.

In a case-comparison study, 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. A review of prospectively collected data of patients who underwent treatment for sialolithiasis by the senior author during 2011 to 2013 was carried out. Patient demographics, operative techniques, surgical findings, clinical outcomes, and
complications were recorded. Additional information regarding symptoms and satisfaction with treatment was obtained via standardized telephone questionnaire at the time of the data analysis. A total of 31 patients were treated for sialolithiasis. Sialoliths averaged 5.9 mm in size (range of 2 to 20 mm) 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). The authors concluded that the findings of this study showed favorable results with the use of intracorporeal holmium laser lithotripsy for the endoscopic management of sialolithiasis with minimal adverse events. The preliminary findings of this small study (n = 16) need to be validated by well-designed studies.

Sionis et al (2014) stated that obstructive sialadenitis is a major cause of dysfunction of the salivary glands, and increasingly sialoendoscopy is used in both diagnosis and treatment. At present the limit of the endoscopic approach is the size of the stone as only stones of less than 4 mm can be removed. Endoscopic laser lithotripsy has the potential to treat many stones larger than this with minimal complications and preservation of a functional salivary gland. The holmium:YAG laser has been widely and safely used in urology, and its use has been recently proposed in salivary lithotripsy for the removal of bigger stones. These researchers described their experience with sialoendoscopy for stones in the parotid and submandibular glands and assessed the feasibility and the effectiveness of holmium:YAG laser lithotripsy. These investigators have used the procedure 50 times for 43 patients
with obstructive sialadenitis; 31 patients had sialolithiasis, 15 of whom (48%) had stones with diameters between 4 and 15 mm (mean of 7 mm). Total extraction after fragmentation was possible in 14 of the 15 patients without complications. The authors concluded that intra-ductal holmium:YAG laser lithotripsy is safe and effective, and allows the treatment of large stones in Stensen's and Wharton's ducts. The main drawback of this study was its small sample size (n = 43 and only 15 had stone diameters between 4 and 15 mm).

An UpToDate review on “Salivary gland stones” (Fazio and Emerick, 2014) states that “Lithotripsy -- For patients in whom a simple trans-oral approach is not possible (typically stones in the proximal ducts or in the salivary glands themselves) or fails, extracorporeal lithotripsy appears to be effective for stones that are intraductal and less than 7 mm. In one prospective study, 76 patients with sonographically detected parotid stones were treated with extracorporeal shock wave therapy after failure of conservative treatment. Fifty percent were free of stones after a follow-up period of 48 months. Twenty-six percent had residual stone fragments detected but were asymptomatic. Laser lithotripsy is an alternative to extracorporeal lithotripsy, and can be performed via an endoscope. This technique is becoming more popular with increasing availability of endoscopy. A preliminary report of clinical use in 17 patients indicated successful treatment of 21 stones with full fragmentation of 5, and partial fragmentation for forceps retrieval or loosening of the remainder”.

The available evidence regarding endoscopic intracorporeal laser lithotripsy is limited and includes studies with small sample size. Well-designed studies (randomized controlled trials and larger sample sizes) are needed to ascertain the effectiveness of this approach.

Wierzbicka et al (2014) noted that shear wave elastography (SWE) is widely used in breast, liver, prostate and thyroid evaluations. Elastography provides additional information if used to assess parotid gland pathology. These researchers
assessed parotid glands by means of SWE to compare the parenchyma properties in different types of inflammation. Prospective analysis included 78 consecutive patients with parotid gland pathology: sialolithiasis (n = 33), Stensen's duct stenosis (n = 15), chronic inflammation (n = 10), and primary Sjogren syndrome (pSS) (n = 20. The primary predictor variable was type of parotid pathology, and secondary predictor variables were patient age and the duration and intensity of complaints. Ultrasound pictures were compared with elastography values of parotid parenchyma. Mean elasticity values for pSS (111 Kilopascals (kPa), Stensen's duct stenosis (63 kPa), sialolithiasis (82 kPa), and chronic inflammation (77 kPa) were significantly higher than the mean value for healthy patients (24 kPa). Elasticity increased proportionally to the intensity of complaints: mild (51 kPa), moderate (78 kPa), and strong (90 kPa). Increased elasticity did not correspond with ultrasonographic pictures. In pSS the parenchyma was almost twice as stiff as in chronic inflammation (p = 0.02), although subjective complaints were mostly mild or moderate, and the ultrasonographic picture did not present features of fibrosis. The authors concluded that sono-elastography, by improving routine ultrasonographic assessment, might be a useful tool for parotid evaluations during the course of chronic inflammation. An extraordinarily high degree of stiffness was revealed in pSS despite lack of fibrosis by ultrasonography and moderate subjective complaints, suggesting that sono-elastography could be a valuable diagnostic tool.

Woo et al (2014) stated that trans-oral removal of stones for the treatment of submandibular sialolithiasis has been popularized, even for stones in the hilum. Without sialodochoplasty after surgical retrieval, the affected glands seem to recover well functionally, even without sialodochoplasty. However, the anatomical changes of structural recovery have not been fully studied. These researchers investigated the outcomes and the changes to the salivary duct system after trans-oral removal of hilar stones using post-operative sialography. They enrolled 28 patients (29 sides) who had trans-oral removal of stones for submandibular
hilar sialolithiasis without sialodochoplasty, and prospectively analyzed the structural outcomes 3 months and 12 months post-operatively using sialography. They found 23 ducts (79 %) recovered with a normal size, while 4 ducts (14 %) developed saccular dilatation and 1 duct (3 %) partially stenosed. Saccular dilatation developed after removal of stones larger than 10 mm in diameter, but patients had no recurrent symptoms. By the 12 months' follow-up, 1 stone had formed severe adhesions to the salivary duct that caused stenosis, and this patient had recurrent symptoms. The authors concluded that trans-oral removal of submandibular hilar stones without sialodochoplasty is an effective treatment with good anatomical restoration of the salivary duct and flow.

**Endoscopic Pneumatic Lithotripsy:**

Walvekar et al (2016) evaluated the effectiveness of endoscopic fragmentation and removal of artificial calculi in a live porcine model employing intracorporeal pneumatic lithotripsy. In this experimental study, a total of 7 submandibular ducts were accessed and artificial calculi placed. A salivary pneumatic lithotripter probe was inserted through an interventional sialendoscope to fragment the calculi. A salivary duct catheter was then used to flush stone fragments, followed by endoscopy to assess complete fragmentation and ductal trauma.

Ultimately, 7 artificial stones (3 to 10 mm, 4F/5F) were successfully fragmented without causing significant endoluminal trauma. Number of pulses for adequate stone fragmentation averaged 20 (range of 5 to 31). In all cases, stone fragments were successfully flushed out with the salivary duct catheter. Post-procedure endoscopy confirmed ductal integrity in all 7 ducts. The authors concluded that while more studies are needed, this preliminary animal model demonstrated the effectiveness of endoscopic pneumatic lithotripsy for the management of sialolithiasis.

In a retrospective study, Koch and colleagues (2016) examined the effectiveness of a newly approved pneumatic lithotripter for fragmentation of salivary stones. A total of 44 patients (49
stones) were treated with direct endoscopic guidance using the StoneBreaker; 23 stones were located in the parotid gland and 26 in the submandibular gland. Complete fragmentation was achieved combined extracorporeal in 97.7% of the stones. All of the patients became symptom free, and 97.7% were stone-free; 3 patients underwent lithotripsy procedures. Altogether additional treatment was necessary in 5 cases to achieve stone clearance. The reason for residual sialolithiasis was intra-parenchymal repulsion of a residual fragment (n = 1). The glands were preserved in all cases. The authors concluded that endoscopically guided intra-ductal pneumatic lithotripsy using the StoneBreaker is an effective and promising procedure for the treatment of sialolithiasis.

<table>
<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</strong></td>
</tr>
<tr>
<td><strong>ICD-10 codes will become effective as of October 1, 2015:</strong></td>
</tr>
<tr>
<td><strong>No specific code for extracorporeal shockwave lithotripsy for the treatment of sialolithiasis, for MR Elastography (MRE) for the evaluation of sialolithiasis, or the endoscopic intracorporeal laser lithotripsy for treatment of sialolithiasis:</strong></td>
</tr>
<tr>
<td><strong>CPT codes not covered for indications listed in the CPB:</strong></td>
</tr>
<tr>
<td>0346T</td>
</tr>
<tr>
<td>42500</td>
</tr>
<tr>
<td>42505</td>
</tr>
<tr>
<td><strong>Other CPT codes related to the CPB:</strong></td>
</tr>
<tr>
<td>42330 - 42340</td>
</tr>
<tr>
<td>78230</td>
</tr>
<tr>
<td>78231</td>
</tr>
</tbody>
</table>
Salivary gland function study

ICD-10 codes not covered for indications listed in the CPB:

- K11.5 Sialolithiasis

There are no specific codes for sialendoscopy (diagnostic or therapeutic):

ICD-10 codes covered if selection criteria are met:

- K11.20 - K11.23 Sialoadenitis [chronic]
- K11.5 Sialolithiasis

The above policy is based on the following references:


25. Fazio SB, Emerick K. Salivary gland stones. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed June 2012.


Copyright Aetna Inc. All rights reserved. Clinical Policy Bulletins are developed by Aetna to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Clinical Policy Bulletin contains only a partial, general description of plan or program benefits and does not constitute a contract. Aetna does not provide health care services and, therefore, cannot guarantee any results or outcomes. Participating providers are independent contractors in private practice and are neither employees nor agents of Aetna or its affiliates. Treating providers are solely responsible for medical advice and treatment of members. This Clinical Policy Bulletin may be updated and therefore is subject to change.

Copyright © 2001-2016 Aetna Inc.
AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0716
Sialolithiasis (Salivary Stones)

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania
Updated 03/2017