Keystone First
Family of Health Plans

Sialendoscopy and lithotripsy for salivary stones

Clinical Policy ID: CCP.1505

Recent review date: 11/2025

Next review date: 3/2027

Policy contains: Extracorporeal shock wave lithotripsy, sialadenitis, sialolithiasis, sialendoscopy, salivary stones, salivary glands, holmium:YAG laser lithotripsy.

Coverage policy

Extracorporeal and endoscopic lithotripsy are investigational/not clinically proven and, therefore, not medically necessary for treatment of salivary stones.

Sialendoscopy is clinically proven and, therefore, may be medically necessary for the management of chronic or recurrent sialadenitis, including sialolithiasis and recurrent parotitis of childhood (Beumer, 2023; Salzano, 2025; Wilson, 2014).

<u>Limitations</u>

No other limitations were identified.

<u>Alternative covered services</u>

- Surgical mucotomy.
- Salivary gland excision.
- Ultrasonography (diagnostic and therapeutic).
- Computed tomography (diagnostic and therapeutic).

Background

Salivary glands secrete saliva and have essential roles in lubricating the oral cavity and aiding in chewing, swallowing, speaking, dental hygiene, and digestion (Hammett, 2022). There are three main paired salivary glands — the parotids, submandibulars, and sublinguals:

- The parotid gland is the largest of the three paired major salivary glands. It is located in the retromandibular fossa. Its main excretory duct is known as Stensen's duct (Chason, 2022).
- The submandibular gland is the second largest of the three main salivary glands. They are paired major salivary glands that lie in the submandibular triangle. The Wharton's duct is the main excretory duct that drains into the oral cavity at the sublingual caruncle. The submandibular gland produces approximately 70% of the saliva in the unstimulated state. However, when the salivary glands become stimulated, the parotid gland's saliva production increases to 50% (Grewal, 2022).
- The sublingual gland is the smallest of the three major salivary glands and is located in the floor of the mouth on each side of the frenulum. A group of excretory ducts, called the ducts of Rivinus, drain the sublingual gland. The largest sublingual gland excretory duct, called the sublingual duct of Bartholin, joins Wharton's duct near the sublingual caruncle. The sublingual gland contributes approximately 5% of saliva in the oral cavity (Grewal, 2023).

Sialadenitis and sialadenosis are common causes of submandibular gland swelling. Submandibular sialadenitis is inflammation of the submandibular gland, which is caused by salivary stasis that leads to retrograde seeding of bacteria from the oral cavity. Sialadenosis is a benign, noninflammatory swelling of salivary glands, usually associated with metabolic conditions (Adhikari, 2022).

Obstructive sialadenitis is a major cause of salivary gland dysfunction. Sialolithiasis is a benign condition involving the presence of mineral calculi (or stones) in the major salivary glands or ducts. The etiology of salivary stones is not well understood but anatomy and saliva composition (e.g., increased calcium content or altered enzyme function) affecting saliva formation or flow may be important factors. Approximately 85% of salivary stones originate in the submandibular gland and are the most common cause of submandibular gland swelling (Hammett, 2022).

High-resolution ultrasound, computed tomography generally without contrast, and magnetic resonance sialography may be employed to diagnose and locate the obstruction; each modality presents its own limitations and benefits. Sialendoscopy permits direct visualization of the salivary ducts and salivary stones (Hammett, 2022).

Increasingly, sialendoscopy is used in both diagnosis and treatment for its more favorable complication profile compared to open surgical techniques. Development of smaller, semi-rigid sialendoscopes has made intraductal removal of salivary stones feasible. It can be performed in the outpatient setting using local anesthesia. Only stones smaller than 4 millimeters can be removed endoscopically. Lithotripsy has the potential to break up larger stones into smaller fragments with minimal complications, permit minimally invasive removal, and preserve a functional salivary gland (Sionis, 2014).

Extracorporeal shock-wave lithotripsy, which uses electromagnetic or piezoelectric shock waves, preceded the introduction of endoscopic alternatives. Several types of lithotripters have been issued 510(k) regulatory approval (U.S. Food and Drug Administration, 2024). They vary depending on the energy used, the approach (extracorporeal and intracorporeal), and the indication. As of this writing, no lithotripter has been approved for removal of salivary stones, which is considered an off-label use.

The goal of treatment is to increase saliva flow through the ducts and induce salivary secretion. Conventional treatment is aimed at the underlying condition (Sionis, 2014):

- Acute sialadenitis. Conservative medical management includes hydration, warm compresses, massage, pain relief, sialagogues, corticosteroids, and empiric antibiotics. Rarely, acute suppurative sialadenitis can lead to abscess formation; surgical incision and drainage are indicated in these cases.
- Chronic sialadenitis. Treatment includes hydration, oral hygiene, pain relief, sialagogues, and possibly antibiotics.
- Sialolithiasis. Salivary gland stone removal is performed using interventional sialendoscopy or direct surgical excision. Extracorporeal shock wave lithotripsy under ultrasound has been attempted for stones not palpable or visualized under endoscopy.
- Recurrent sialadenitis (more than three episodes per year) or chronic sclerosing sialadenitis. Excision of the salivary gland is the usual recommendation.

Findings

Sialendoscopy is an established diagnostic and therapeutic tool in the management of salivary gland disorders for its ability to directly visualize obstruction and facilitate minimally invasive treatment. Sialendoscopy-assisted techniques have diffused into practice as attractive minimally invasive, gland-preserving alternatives, despite a lack of conclusive evidence from randomized trials supporting their effectiveness relative to other gland-sparing alternatives.

Guidelines

There is general agreement among limited professional guidance that sialendoscopy using grasping forceps, wire baskets, and graspers can be used to remove salivary stones, but there is a lack of agreement on the clinical value of lithotripsy as a treatment adjunct. The National Institute for Health and Care Excellence (2007) recommends surgical excision, interventional sialography, and extracorporeal or endoscopic lithotripsy, depending on the size, morphology, and location of the calculi. Excision of the salivary gland may be required for large or less accessible stones. Their recommendations were based on positive safety and efficacy data from five case series.

The American Academy of Family Physicians stated ultrasonography and non–contrast-enhanced computed tomography are accurate in detecting sialoliths. Treating any acute infection and surgical removal of the stone is recommended, but the choice of surgical approach used to remove the stone will depend on its location. Sialendoscopy is useful in treating causes of chronic or recurrent sialadenitis, including sialolithiasis and recurrent parotitis of childhood, but the guideline did not mention the use of lithotripsy (Wilson, 2014).

The American College of Radiology (2022) recommends ultrasound for the evaluation of nonneoplastic conditions of the parotid and submandibular glands (e.g., sialolithiasis) and for guiding interventional procedures. It represents a radiation-free imaging alternative useful for detecting calculi in the salivary glands.

Evidence reviews

Evidence quality and study characteristics

The evidence base for salivary lithotripsy consists primarily of small, retrospective feasibility studies with a high risk of bias. A recent comprehensive systematic review by Beumer (2024) analyzed 91 studies comprising 8,218 patients undergoing 9,043 sialendoscopic procedures across both submandibular and parotid glands, with the majority of studies demonstrating medium to high risk of bias. For parotid-specific sialolithiasis, Salzano (2025) identified 42 studies involving 1,559 patients, finding similar methodological limitations including the absence of randomized controlled trials and considerable heterogeneity in patient selection, stone characteristics, and surgical techniques.

Intraductal holmium laser and extracorporeal shock wave lithotripsy were the most studied modalities in earlier reviews. Additional techniques examined include pneumatic lithotripsy and various other laser types (erbium, pulsed excimer, pulsed dye, carbon dioxide, and thulium) (Chiesa-Estomba, 2021). Most enrolled adult participants and, to a lesser extent, pediatric participants with mid-size salivary stones of the parotid or submandibular glands that were considered too large for simple basket retrieval.

Overall effectiveness across treatment modalities

Beumer (2024) reported an overall weighted pooled success rate of 80.9% (95% CI: 76.6-84.6) for sialendoscopy across all salivary glands after a mean follow-up of 20.3 months. Sialendoscopy was significantly more successful in treating patients with sialoliths (89.6%; 95% CI: 85.7-92.5) compared to stenoses (56.3%; 95% CI: 48.7-63.6; p=0.01). The success rate for submandibular glands (88.3%; 95% CI: 82.4-92.4) did not significantly differ from parotid glands (81.2%; 95% CI: 73.4-87.1; p=0.09).

Parotid-Specific Treatment Outcomes

For parotid sialolithiasis specifically, Salzano (2025) demonstrated that treatment approach significantly impacts outcomes:

Endoscopy-Assisted Approaches: Endoscopy-assisted stone removal via intraoral or transfacial approaches achieved the highest stone-free rate (93%, 95% CI: 90-96) and symptom improvement rate (91%, 95% CI: 92-99) (p<0.05). These combined approaches integrate endoscopic precision with external surgical access, proving particularly effective for complex and large stones (>6 mm), intraparenchymal locations, stones adherent to the duct wall, or cases with prior procedural failures. Beumer (2024) reported similar findings, with endoscopic-assisted transoral removal achieving an 86.3% success rate.

Pure Sialendoscopy: Interventional sialendoscopy alone demonstrated a pooled stone-free rate of 83% (95% CI: 44-97) for parotid stones (Salzano et al., 2025), with Beumer (2024) reporting comparable results. This minimally invasive approach remains valuable for smaller, more accessible stones, though it may fail in cases with large stones or proximal duct involvement, especially when distal strictures or stenosis are present.

Extracorporeal Shock Wave Lithotripsy (ESWL): ESWL demonstrated lower stone-free rates but reasonable symptom control. Salzano (2025) found a pooled stone-free rate of 58% (95% CI: 0.47-0.69) with considerable between-study heterogeneity, but symptom improvement remained high at 86% (95% CI: 0.76-0.93). ESWL is generally effective for stones smaller than 7 mm but shows a failure rate of approximately 10%, primarily in cases involving larger or impacted stones. The main limitations include the need for multiple sessions and residual stone fragments inside the duct system.

CT Navigation-Assisted Approaches: Three studies examined CT navigation-assisted intraoperative localization for impacted parotid sialoliths during combined-approach extraction surgery, yielding a pooled stone-free rate of 80% (95% CI: 0.62-0.91) (Salzano et al., 2025). While CT guidance may enhance localization, surgical failure was significantly associated with stone depth greater than 12 mm (p<0.05), suggesting that deeply embedded stones pose unique challenges irrespective of localization method.

Laser-assisted lithotripsy

A systematic review of laser-assisted lithotripsy with sialendoscopy analyzed 16 nonrandomized studies, including various laser types with holmium being most common (Chiesa-Estomba, 2021). The mean maximum diameter of lithiasis was 7.11 millimeters (range 2-17 millimeters). Success rates (symptom resolution) ranged from 71% to 100% with a mean of 87.3% (SD: 7.21; 95% CI: 5.326-11.158), and gland preservation rates reached 97%. For "nonretrievable-non floating stones," the evidence suggests laser-assisted lithotripsy with sialendoscopy could be a conservative, safe, efficient, and gland-preserving alternative in experienced hands when the indication is appropriate (Chiesa-Estomba, 2021). Salzano (2025) reported that endoscopic YAG-holmium laser treatment achieved a 95% stone-free rate and 100% symptom improvement rate in one included study.

Ozdemir (2020) directly compared intraductal pneumatic lithotripsy with holmium laser-assisted lithotripsy in 51 participants with submandibular gland sialolithiasis. Stones were completely extracted in 95.6% of the holmium-assisted laser lithotripsy group and 92.8% of the pneumatic lithotripsy group, with no significant differences in outcomes between methods ($p>0.05$). Both treatments were effective, minimally invasive, and achieved success rates higher than 90% when performed by experienced surgeons with appropriate participant selection.

Pediatric populations

A systematic review of 40 case reports or case series and one letter (n=243) examining pediatric sialolithiasis found a mean age of 9.7 years (range 16 months to 16 years) (Chen, 2022). Most were single stones (71%), located in the submandibular gland (85.4%), with an average size of 7.7 millimeters (range 1.3-35 millimeters). Over time, the preferred diagnostic imaging modality has shifted from plain radiograph to ultrasound (47.4% of cases), and preferred treatment has shifted from submandibular gland excision to sialendoscopy (52.1% by 2020), often combined with duct dilation, papillotomy, intracorporeal laser lithotripsy, or concurrent transoral incision. Extracorporeal shock wave lithotripsy had the highest complication rate (54.2%) but with a smaller sample size than sialendoscopy. Residual stone fragments requiring re-operation was the most common complication for both ESWL and sialendoscopy (Chen, 2022).

Safety and complications

The evidence suggests lithotripsy modalities are feasible and safe in experienced hands. Salzano (2025) found that combined endoscopic-external approaches, while highly effective, had higher complication rates (24%, 95% CI: 14-37) compared to pure endoscopy (20%, 95% CI: 0.06-0.50) and ESWL (22%, 95% CI: 0.02-0.83), though these differences were not statistically significant ($p=0.1061$). Importantly, no permanent facial nerve injuries were reported, with most complications being minor including postoperative swelling (most common), sialoceles, temporary paresthesia, ductal perforation, salivary fistula, stenosis, and postoperative infection.

Beumer (2024) reported sialadenectomy incidence varying from 0% to 14% across studies, with an overall low need for subsequent sialadenectomy (4.6%). In pediatric patients, sialendoscopy was associated with higher rates of duct injury than other interventions, likely related to endoscopic experience (Chen, 2022).

For pneumatic lithotripsy specifically, Koch (2022) reported an overall complication rate of 4.84% with no differences between submandibular and parotid glands. A 2024 study found that six participants expressed pain or discomfort during Holmium:YAG laser lithotripsy under local anesthesia that limited increases in power and procedure duration, though the procedure was generally well-tolerated.

Anatomical and technical considerations

Along with salivary stone location, ductal anatomy, limited availability of adjunctive options, and provider skill limit widespread use of intraductal approaches. Stone location emerged as a crucial factor for treatment success; for parotid stones, those anterior to the masseter muscle had significantly higher removal rates with sialendoscopy alone compared to those posterior to this anatomical landmark (Salzano et al., 2025). For stones located intraparenchymally and not accessible surgically or sialendoscopically, extracorporeal shock wave lithotripsy with ultrasonographic guidance has been applied alone or in combination with other approaches, where available.

The location and size of stones were reported in limited studies. Mean stone sizes varied by treatment approach: 5.88 mm (95% CI: 4.41-7.36) in the pure endoscopy group, 7.8 mm (95% CI: 7.10-8.50) in the endoscopy-assisted group, and 6.29 mm (95% CI: 6.01-6.57) in the ESWL group (Salzano et al., 2025).

Disease-specific populations

Beumer (2024) analyzed success rates for specific conditions. The weighted pooled success rate for juvenile recurrent parotitis (JRP) was 67.0% (95% CI: 53.1-78.4), significantly higher than for radioactive iodine-induced sialadenitis (RAIS) at 45.8% (95% CI: 26.9-66.0; p<0.01). This difference likely reflects variations in underlying pathophysiology, with RAIS patients experiencing additional symptoms like xerostomia and distinct histopathologic changes in the glandular parenchyma.

Cost-effectiveness and quality of life

Jokela (2019) analyzed costs and health-related quality of life in 260 participants managed with sialendoscopy. Sialendoscopy appeared to improve symptoms and health-related quality of life in participants with salivary stones, but not clearly in those with sialadenitis without salivary stones. Since costs related to sialendoscopy were substantial during two-year follow-up, the cost-effectiveness for treating sialadenitis without salivary stones has not been established and warrants further study. A cost analysis comparing laser-assisted lithotripsy with sialendoscopy to other techniques was not possible due to absence of data (Chiesa-Estomba, 2021).

Evidence limitations and future directions

Multiple systematic reviews identified significant evidence gaps. In the absence of randomized studies comparing laser-assisted lithotripsy against other lithotripsy techniques, proper comparisons or meta-analysis remain impossible (Chiesa-Estomba, 2021). Both Beumer (2024) and Salzano (2025) noted that heterogeneity regarding stone size, instrumentation, surgical expertise, and study design limits definitive conclusions about optimal patient selection and relative effectiveness of different approaches.

The operator learning curve represents an important but understudied factor, with significant improvements in operative time and performance observed after the first 10-30 patients in some studies (Salzano et al., 2025). Salzano (2025) emphasized that high degree of heterogeneity across studies—including variability in patient selection, stone characteristics, surgeon experience, and evolving technology—limits the precision and generalizability of pooled outcomes.

Investigators have proposed prospective, multi-center, randomized studies to compare the safety and effectiveness of different types of intraductal lithotripsy (laser versus pneumatic), intraductal versus external modalities, and validated symptom and quality of life scores before and after each procedure (Chiesa-Estomba, 2021). Additional studies are needed to determine optimal parameters for achieving effective stone fragmentation (Koch, 2022) and to establish standardized definitions of success, complications, and follow-up protocols.

References

On September 17, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “holmium laser lithotripsy,” “extracorporeal shock wave lithotripsy,” “sialendoscopy,” “salivary stones,” “sialadenitis,” “sialolithiasis,” “sialolithotomy,” and “lithotripsy” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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