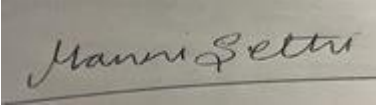


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	Submission Date: 1/2/2025
Policy Number: ccp.1505	Effective Date: 12/2021 Revision Date: November 1, 2024
Policy Name: Sialendoscopy and lithotripsy for salivary stones	
Type of Submission – Check all that apply: <div style="margin-left: 20px;"><input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL</div>	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any clarifying information for the policy below:</p> <p>See tracked changes below.</p>	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Sialendoscopy and lithotripsy for salivary stones

Clinical Policy ID: CCP.1505

Recent review date: 11/2024

Next review date: 3/2026

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

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

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 (Wilson, 2014).

Limitations

No other limitations were identified.

Alternative covered services

- 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

From the evidence reviewed in this policy, intraductal holmium laser and extracorporeal shock wave were the most studied lithotripsy modalities. The best available evidence consists of small, retrospective feasibility studies with a high risk of bias. 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. Sialendoscopy was often combined with surgical excision and extracorporeal shock wave lithotripsy for successful stone removal, symptom improvement, and gland-preserving treatment. The evidence suggests lithotripsy modalities are feasible and safe in experienced hands. The heterogeneity and retrospective nature of

the evidence limits the conclusions about optimal patient selection and the relative effectiveness of different lithotripters and other gland-sparing treatment alternatives.

Along with salivary stone location, ductal anatomy and limited availability of adjunctive options and provider skill limit widespread use of intraductal approaches. 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 main limitations of extracorporeal treatment are the need for multiple sessions and residual stone fragments inside the duct system.

A systematic review of 40 case reports or case series and one letter (n = 243) reported demographic characteristics, diagnosis, and treatment outcomes of pediatric sialolithiasis. The mean age was 9.7 years (range 16 months to 16 years). Most were single stones (71%), located in the submandibular gland (85.4%), and had an average size of 7.7 millimeters (range 1.3 to 35 millimeters). Over time, the preferred diagnostic imaging modality has shifted from plain radiograph to ultrasound (47.4% of cases), and the 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. Sialendoscopy was associated with higher rates of duct injury than other interventions, likely related to endoscopic experience. Residual stone fragments requiring re-operation using another procedure type was the most common complication for both extracorporeal shock wave lithotripsy and sialendoscopy (Chen, 2022).

Another systematic review analyzed the safety and efficacy of laser-assisted lithotripsy with sialendoscopy in the treatment of sialolithiasis. A total of 16 nonrandomized studies met inclusion criteria. The following lasers were included in the analysis: Erbium (one study); pulsed excimer (one); pulsed dye (two); carbon dioxide (one); Thulium (one); Holmium (nine); and laser type not reported (one). The mean maximum diameter of lithiasis was 7.11 millimeters (range 2 to 17 millimeters). Success rate (symptom resolution) ranged from 71% to 100% with a mean of 87.3% (standard deviation: 7.21; 95% confidence interval: 5.326 to 11.158), and the gland preservation rate was 97% (Chiesa-Estomba, 2021).

Considering only studies with "nonretrievable-non floating stones," eight retrospective, non-randomized studies and one prospective, non-randomized study reported results from parotid and submandibular gland lithiasis. The most common gland involved was the submandibular gland (n = 153; 65.1%), in comparison to the parotid gland (n = 82; 34.8%). The evidence suggests laser-assisted lithotripsy with sialendoscopy could be a conservative, safe, efficient, and gland-preserving alternative approach, in experienced hands, for management of mid-size sialolith removal from major salivary glands, when the indication was appropriate (Chiesa-Estomba, 2021).

The authors reported several limitations in the evidence base. In the absence of randomized studies comparing laser-assisted lithotripsy against other lithotripsy techniques, it was impossible to establish proper comparisons or perform a meta-analysis. Also, there was heterogeneity regarding stone size, instrumentation, and surgical expertise, and by the exclusion of studies due to the lack of relevant data. A cost analysis of laser-assisted lithotripsy with sialendoscopy in comparison with other techniques was not possible due to the absence of data. The investigators 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).

Ozdemir (2020) analyzed the indications, outcomes, and reliability levels of the intraductal pneumatic lithotripsy and holmium laser-assisted lithotripsy methods in 51 participants with submandibular gland sialolithiasis. Intraductal pneumatic lithotripsy was used to break up 32 stones in 28 participants, while holmium-assisted laser lithotripsy was used to break up 28 stones in 23 participants. The stones could be completely extracted in 95.6% of the participants in the holmium-assisted laser lithotripsy group, 92.8% of those in the intraductal pneumatic

lithotripsy group, and 94.1% of all participants. The complete and partial recovery rates of the participants were respectively 91.3% and 8.7% in the holmium assisted laser lithotripsy group, and 92.8% and 7.2% in the intraductal pneumatic lithotripsy group.

There was no significant difference based on the lithotripsy method that was used in the participants' laterality of stones, location of stones, stone diameter, operation time, need of papillotomy and silicone stent, complete removal status of stones and the symptomatic assessments of the participants in the sixth postoperative month. The authors concluded that both holmium-assisted laser lithotripsy and intraductal pneumatic lithotripsy treatments were effective, minimally invasive, and promising methods in difficult/complex submandibular gland sialolithiasis treatments that may provide success rates of higher than 90% when they were performed by an experienced surgeon and by selection of appropriate participants (Ozdemir, 2020).

Jokela (2019) analyzed the costs of sialendoscopy and impact on health-related quality of life of 260 participants with sialolithiasis and sialadenitis managed with sialendoscopy at a tertiary care university hospital in Finland between January 2014 and May 2016. Sialendoscopy appeared to improve symptoms and health-related quality of life in participants with salivary stones, but not clearly so in those with sialadenitis without salivary stones. Since the costs related to sialendoscopy were substantial during the two-year follow up, the authors determined the cost effectiveness of sialendoscopy for treatment of sialadenitis without salivary stones has not been established and warrants further study.

In 2022, we updated the references and added three guidelines, one systematic review (Chen, 2022), and one nonrandomized study (Jokela, 2019), which confirm previous policy findings. We deleted several older references already analyzed in the systematic reviews. We eliminated the coverage statement on imaging, as imaging medical necessity criteria are addressed in other corporate source materials.

In 2023, we added one retrospective case series of 62 participants who received pneumatic lithotripsy for treating salivary stones (43 submandibular and 34 parotid stones) alone or as part of multimodal treatment. Pneumatic lithotripsy achieved complete fragmentation rates of 98.7%, stone-free rate of 90.32%, and symptom-free rates of 100%. Pneumatic lithotripsy successfully treated multiple stones in 24.19% of participants as part of multimodal therapy with complete gland preservation. The overall complication rate was 4.84% with no differences in the frequency of complications between submandibular and parotid glands. Additional studies are needed to determine the optimal parameters for achieving effective stone fragmentation (Koch, 2022). No policy changes are warranted.

In 2024, we added a retrospective study of 42 participants with 48 salivary stones treated with Holmium:YAG laser-assisted sialendoscopic intraductal lithotripsy under local anesthesia. Mean stone size was 6.2 mm. Complete and incomplete fragmentation was achieved in 66.7% and 33.3% of cases, respectively. Half of the 14 cases with incomplete fragmentation remained symptom free on follow-up. The procedure was generally well-tolerated, but six participants expressed pain or discomfort that limited increases in power and procedure duration. These findings are consistent with previous policy findings and warrant no policy changes.

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On September 17, 2024, 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

11/2021: initial review date and clinical policy effective date: 12/2021

11/2022: Policy references updated. Coverage and title modified.

11/2023: Policy references updated.

11/2024: Policy references updated.

