SUBJECT: SIALENDOSCOPY

POLICY NUMBER: 7.01.94
CATEGORY: Technology Assessment

EFFECTIVE DATE: 04/19/18
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- If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
- If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT:
Based on our criteria and assessment of the peer-reviewed literature, use of sialendoscopy for diagnostic or therapeutic purposes has been medically proven to be effective and is considered medically appropriate for the management of chronic sialadenitis and sialolithiasis (salivary duct stones).

POLICY GUIDELINES:
I. If sialendoscopy is performed in conjunction with another salivary duct/gland surgery, the sialendoscopy would be considered inclusive/incidental to the primary procedure, and therefore, would not be allowed separate reimbursement.

II. Acute sialadenitis is a contraindication for sialendoscopy. Although this condition is not an absolute contraindication, acute inflammation makes sialendoscopy problematic because an inflamed ductal system is more difficult to dilate and use of a dilator system and scope increases the chance of ductal trauma and can foster the spread of infection.

DESCRIPTION:
Traditional methods of treating nonneoplastic disorders of the salivary gland include watchful observation, medical treatment, and surgical excision of the involved salivary gland. Sialendoscopy is a relatively new procedure that allows endoscopic transluminal visualization of major salivary glands and offers a mechanism for diagnosing and treating both inflammatory and obstructive pathology related to the ductal system.

Sialendoscopy offers a minimally invasive approach to disease management and can be both diagnostic and therapeutic. It is complementary to diagnostic techniques such as plain radiography, ultrasonography, computed tomography (CT), magnetic resonance sialography, and conventional sialography, all of which are traditional, time-tested methods for evaluating the salivary ductal system. The most common nonneoplastic pathology for which sialendoscopy is indicated is salivary stones. The most common area of origin for sialoliths (80%) is the submandibular gland. Nineteen percent occur in the parotid gland, and 1% are found in the sublingual glandular system. Sialolithiasis is most frequently found in adults, but it may also present in children. Sialolithiasis is a major cause of sialadenitis and unilateral diffuse swelling of the major salivary glands. Other common indications for sialendoscopy include diagnostic evaluation of recurrent unexplained swelling of the major salivary glands associated with meals, ductal stenosis, and intraductal masses.

Endoscopic stone removal is recommended for stones smaller than 4 mm in submandibular cases and smaller than 3 mm in parotid cases. When the stones are very large or when preoperative assessment suggests that endoscopic removal will be difficult, combined surgical approaches have been employed.

Sialendoscopy includes progressive dilatation of the salivary duct, with or without stents, performed until the opening is large enough to allow the introduction of an endoscope. The duct is irrigated initially with a local anaesthetic solution and then with saline as the scope is passed through the ductal system. Instruments (such as wire retrieval baskets) are then introduced through the endoscope to remove stones. A stent may sometimes be left in the duct postoperatively.
RATIONALE:

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. Across these studies therapeutic sialendoscopy relieved duct obstruction in between 82% (90/110) and 87% (47/54) of cases.

Based on a weighted pooled analysis (Strychowsky, et al. 2012), success rates for interventional sialendoscopy alone (1,213 patients) has been reported at 86%, and 93% for sialendoscopy with a combined surgical approach (374 patients).

A study of 1,154 patients Zenk and colleagues (2012) reported high stone and symptom-free success rates of 100% and 98% for sialendoscopy alone in submandibular and parotid cases, respectively. Additionally, long-term success was greater than 90% for patients with submandibular and parotid stones treated with sialendoscopy.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: There is no specific CPT code for sialendoscopy; however, 42699 (unlisted procedure, salivary gland or ducts) may be billed

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HCPCS: No specific code

ICD 10: K11.5 Sialolithiasis
        K11.23 Chronic sialadenitis

REFERENCES:


* key article

**KEY WORDS:**
Salivary duct, Salivary gland, Salivary stone, Sialadenitis, Sialolithiasis

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, sialendoscopy is not addressed in National or Regional Medicare coverage determinations or policies.