Clinical Policy Bulletin: Surgical Treatments to Control Drooling (Sialorrhea)

Number: 0265

Policy

Aetna considers surgical correction of refractory excessive drooling medically necessary for members who meet both of the following criteria.

1. Members must have excessive drooling that is associated with significant morbidity such as skin maceration, poor oral hygiene or dehydration; and
2. Members must have failed to adequately respond to appropriate physical therapy and drug therapy.

The following surgical procedures to control excessive drooling may be considered medically necessary for members who meet the selection criteria listed above:

1. Excision of submandibular gland, with or without parotid duct ligation
2. Parotid duct diversion, bilateral (Wilke type procedure)
3. Parotid duct diversion, bilateral, with excision of one submandibular gland
4. Parotid duct diversion, bilateral, with excision of both submandibular glands
5. Parotid duct diversion, bilateral, with ligation of both submandibular ducts
6. Relocation of the submandibular ducts, with or without removal of sublingual glands
7. Tympanic neurectomy or chorda tympani neurectomy.

Aetna considers surgical correction of drooling cosmetic when criteria are not met.

Aetna considers transoral submandibular ganglion neurectomy experimental and investigational for correction of drooling because the effectiveness of this approach has not been established.

See also CPB 0113 - Botulinum Toxin.

Background
Excessive drooling (sialorrhea, ptyalism) is estimated to occur in 10% of patients with cerebral palsy (CP), and in other patients with neurological damage. While drooling can be considered a cosmetic problem, excessive drooling can result in significant hygienic problems, maceration of the skin and dehydration. Furthermore, excessive drooling can limit any efforts at speech therapy.

Drooling can either be related to a central neurogenic problem, as in CP, in which there is poor coordination of the muscles of deglutination, or be related to a peripheral nerve lesion, such as in facial nerve or glossopharyngeal nerve palsy. All patients should initially be treated with various physical therapy and behavior modifications regimens. Medical therapy has focused on the use of anti-cholinergic drugs, which reduce the production of saliva. However, therapeutic doses of these drugs usually result in unacceptable side effects such as constipation, urinary retention, blurred vision and restlessness. When conservative approaches fail, surgical intervention can be considered.

Surgical management of sialorrhea includes rerouting the parotid or submandibular ducts, excision of the submandibular glands or transection of the nerves innervating the parotid gland (tympanic neurectomy) or submandibular gland (chorda tympani neurectomy). Although none of the procedures has been studied in large series of patients, all seem to be associated with a success rate of greater than 82%. Selection of the procedure seems to be largely a physician/patient preference issue, balancing the increased morbidity of the gland excision or duct relocation procedures against the threat of recurrence and the loss of taste associated with the neurectomy procedures.

Glynn and O'Dwyer (2007) stated that submandibular duct relocation plus or minus excision of the sublingual glands are relatively simple procedures with low morbidity. In a prospective study, these researchers compared both procedures including operative time, length of hospital stay, post-operative complications, drooling scores and parental satisfaction. A total of 71 submandibular duct relocation and 29 submandibular duct relocation plus excision of the sublingual glands procedures were performed. Exclusion criteria were patients with recurrent aspiration pneumonias or dental caries. Two patients were lost to follow-up and excluded from the study. Operative time and length of hospital stay were increased in the submandibular duct relocation plus sublingual gland excision group. Drooling scores and parental satisfaction results were excellent, 93% of parents in the submandibular duct relocation group and 89% of parents in the duct relocation plus sublingual glands excision were satisfied and would recommend the procedure. There was no statistical difference (p = 0.643) in drooling scores between the 2 procedures. Post-operative morbidity was higher with the addition of sublingual gland excision, with post-operative hemorrhage occurring in 13.7% and 36% of parents expressing concern over post-operative pain, compared with 3% post-operative hemorrhage rate with submandibular duct relocation and only 12% of parents expressing the same concerns. The authors concluded that both procedures are effective in drooling control, but the addition of sublingual gland excision increases morbidity. These researchers no longer excise sublingual glands with submandibular duct relocation.

Celet Ozden et al (2012) noted that drooling complicates many neurologic disorders including CP. Surgical treatment consists mainly of ablative
(excision/ligation) or physiological (diversion) methods; combined techniques have also been proposed. These investigators have applied bilateral diversion of both submandibular and parotid ducts in 12 CP patients (age range of 7 to 15 years). Pre-operative drooling severity was grade 4/5 in 10 cases and grade 5/5 in 2 of the cases. All patients underwent physiotherapy for a minimum of 6 months and were consulted with a dentist, otolaryngologist, and a speech therapist before surgery. No bleeding, hematoma, or infection has been observed in any of the patients. Two patients had early post-operative tongue edema that regressed with conservative treatment. All patients except 1 regressed to grade 2/5 drooling by the first post-operative month. In 1 patient who had previously been classified as grade 5/5, surgery provided limited improvement with only 1 grade of step-down. Satisfactory results for the patients and their families could be achieved and sustained for a median 18 months (7 to 20 months) of follow-up. The authors concluded that the quadruple duct diversion method is an effective physiological surgical method in the control of drooling in CP.

In a prospective, non-randomized interventional study, Chanu et al (2012) evaluated the improvement in drooling in children undergoing 4-duct ligation procedure for excessive drooling and studied its effect on their quality of life. A total of 30 drooling children of both sexes aged 4 to 15 years underwent 4-duct ligation (i.e., ligation of bilateral submandibular ducts and bilateral parotid ducts). Comparison of pre-operative and post-operative drooling scores using Thomas-Stonell and Greenberg classification was done. Glasgow Children's Benefit Inventory Score was used to assess the improvement in the quality of life. Success rate in terms of improvement in drooling was 93.33 %. A complication rate of 16.67 % was found. The mean improvement in total drooling score after 12 months was 4.43. The paired t-test applied on pre-operative and post-operative combined drooling scores showed p < 0.001. The mean Glasgow Children's Benefit Inventory score was 36.15. In the post-operative period, transient swelling of cheeks, transient swelling of submandibular glands, change in the consistency of saliva, cheek abscess, collection of saliva in the cheek, and parotid duct fistula were observed. The authors concluded that the 4-duct ligation resulted in marked improvement in drooling and significantly increased the quality of life in drooling children. It has few complications, which can be managed effectively.

Stern et al (2002) evaluated the safety of bilateral submandibular gland excision (SGE) with parotid duct ligation (PDL) and assessed its long-term complications and effectiveness in the treatment of chronic sialorrhea in children. A total of 93 patients with chronic sialorrhea who underwent bilateral SGE with PDL from 1988 to 1997 were included in this study. Main outcome measures included operative and post-operative complications, length of post-operative hospitalization, post-operative drooling, care requirements, xerostomia, dental caries, and overall satisfaction. The mean post-operative stay was 2.4 days. There were 3 post-operative complications. Seventy-two families were interviewed (follow-up time, 1 to 10 years): 62 (87 %) reported no further drooling or significant improvement; 7 reported the occurrence of dry mouth; and 2 reported an increase in dental caries. The authors concluded that bilateral SGE with PDL is a safe and consistently efficient procedure for the treatment of chronic sialorrhea in children.

Noonan et al (2014) noted that sialorrhea and chronic salivary aspiration are a major problem in many neurologically impaired children causing embarrassment,
skin issues and recurrent lower respiratory tract infections (LRTI). These researchers evaluated the effectiveness of salivary gland surgery in the treatment of chronic salivary aspiration in such children. They compared admission rates for LRTI per annum before and after surgical intervention. These investigators performed a retrospective review of all patients who underwent salivary management surgery for chronic aspiration under Princess Margaret Hospital’s (PMH) Otolaryngology department from 2006 until 2013. A total of 12 patients were included in this review. Their ages ranged from 3 to 21 years (mean of 11.4). Their genders were equally distributed. Two patients had underlying congenital disorders; 1 had an acquired brain injury, while the majority (n = 9, 75 %) had cerebral palsy secondary to a sustained perinatal injury. Most patients (n = 11, 91.7 %) had bilateral SGE and PDL as a primary procedure. One patient had a laryngo-tracheal separation. Two patients went on to have a second procedure. The mean follow-up time was 5 years. Using Wilcoxon Signed-Rank test, these researchers showed that the median rate of admission per annum for LRTI pre-operatively was 1.0. This was reduced to 0.5 post-operatively, which was statistically significant (p ≤ 0.05). The authors hypothesized that the combination of bilateral SGE and bilateral PDL is effective in reducing admissions with aspiration pneumonia in neurologically impaired children, and therefore improves the quality of life in these patients.

Naghavi and Jalali (2010) assessed the results following submandibular duct relocation and sublingual resection for the treatment of drooling. These researchers presented the results of the surgical protocol used between 1994 and 2007 at the Drooling Clinic of Amiralmomenen Hospital in Rasht, Iran (n = 32). The pre-operative and post-operative levels of drooling were measured. The parents of the patients were contacted by telephone at least 1 year after operation. Of all the patients, 18 were males and 14 were females; and were aged 6 to 26 years. Of 30 patients with complete patients’ chart, the mean drooling score fell from 7.59 to 2.71 after surgery (p < 0.0001). In 30 patients, results of operation were ascertained by telephone at average of 5.6 years after operation. In 78.1 % of patients, long-term result was successful and none was considered worse after the procedure. There were few complications, none of which had any long-term adverse effects. Swelling of submandibular glands was frequently observed in the immediate post-operative period. Only 1 ranula was seen as delayed complication. The authors concluded that submandibular duct relocation with simultaneous sublingual gland excision is a safe and consistently efficient procedure for the treatment of chronic sialorrhea.

Hornibrook and Cochrane (2012) reviewed the causes of severe sialorrhea, and in particular in children in whom it can become a life-long disability. These investigators also discussed history of medical and surgical treatments. A major advance has been the surgical relocation of the submandibular gland ducts with removal of sublingual glands. The results of this operation, technical considerations, and its outcomes in 16 children were presented. There were no significant complications. Caregivers judged the effectiveness with a median score of “75 %” improvement. The technique has become the most logical and reliable surgical treatment for drooling, with very good control in most cases. In contrast to "Botox", its effects are permanent.
Formeister et al (2014) stated that chronic sialorrhea is a common problem for pediatric patients with disorders that affect swallowing. While many patients are successfully treated with medical therapies such as Robinul (glycopyrrolate) and scopolamine, a number of such children are not able to tolerate the side effects of these medications. In these cases, surgical treatments can include botulinum toxin A (Botox) injections into the major salivary glands, sublingual or submandibular gland excision (SMGE), submandibular duct ligation, PDL, or any combination of the above procedures. These investigators reported on the 10-year experience with the surgical management of chronic sialorrhea at 1 tertiary care institution, and compared the efficacy of open surgical procedures versus Botox injections for reduction in salivary flow. A retrospective chart review identified 27 pediatric patients with chronic sialorrhea; 21 of whom underwent Botox injections and 15 of whom underwent surgical procedures. Pre-operative and follow-up clinic notes were reviewed to determine the level and severity of drooling as well as the effectiveness of sialorrhea reduction, as assessed by the Teacher Drooling Scale (TDS). A total of 42% of those receiving Botox injections reported a reduction in drooling, with the average pre- and post-Botox TDS of 4.3 and 3.9, respectively (p = 0.02 by the Wilcoxon signed rank test); 9 of the patients receiving Botox injections (43%) required multiple injections, with an average duration of effect of 3.9 months, and 7 patients (33%) eventually required surgery. All of the children who underwent surgery (7 bilateral SMGE with PDL, 6 SMGE only, and 2 PDL only) experienced a reduction in drooling, with average pre- and post-operative TDS of 4.5 and 2.2, respectively. This reduction was significant by the Wilcoxon signed rank test (p = 0.001). The authors concluded that the 10-year experience at their institution demonstrated the safety, effectiveness and long-term control of drooling in the patients undergoing surgery for intractable sialorrhea.

Spock et al (2014) explored the feasibility of transoral submandibular ganglion neurectomy for the management of sialorrhea. A total of 10 human cadaver dissections of the floor of mouth were performed bilaterally, for a total of 20 separate cases. A transoral submandibular ganglion neurectomy was performed in 10 cadavers (20 neurectomies) easily and reliably, without injury to the submandibular duct or the main trunk of the lingual nerve. The authors concluded that transoral submandibular ganglion neurectomy is an attractive addition to the armamentarium of surgical options for the treatment of medically intractable sialorrhea. They stated that further study in selected patients is needed to demonstrate clinical feasibility.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>42440</td>
<td>Excision of submandibular (submaxillary) gland</td>
</tr>
<tr>
<td>42507</td>
<td>Parotid duct diversion, bilateral (Wilke type procedure)</td>
</tr>
<tr>
<td>42509</td>
<td>with excision of both submandibular glands</td>
</tr>
</tbody>
</table>
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42510 with ligation of both submandibular (Wharton's) ducts

69676 Tympanic neurectomy

**Other CPT codes related to the CPB:**

42500 Plastic repair of salivary duct, sialodochoplasty; primary or simple

42505 secondary or complicated

42550 Injection procedure for sialography

70390 Sialography, radiological supervision and interpretation

**HCPCS codes covered if selection criteria are met:**

D7981 Excision of salivary gland, by report

**Other HCPCS codes related to the CPB:**

D0310 Sialography

**ICD-9 codes covered if selection criteria are met:**

527.1 Hypertrophy of the salivary glands

**Other ICD-9 codes related to the CPB:**

343.0 - 343.9 Infantile cerebral palsy

351.0 - 351.9 Facial nerve disorders

352.2 Other disorders of glossopharyngeal [9th] nerve

527.2 Sialoadenitis

527.3 Abscess of the salivary glands

527.7 Disturbance of salivary secretion

The above policy is based on the following references: