Clinical Policy Bulletin: Paralytic Lagophthalmos Treatments

Number: 0366

Policy

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

Aetna considers gold-weight or platinum-weight eyelid implants, or palpebral springs medically necessary for members with paralytic lagophthalmos (incomplete closure of the eyelids) as an alternative to medical therapy or tarsorrhaphy when all of the following selection criteria are met:

- Members are expected to have delayed, incomplete recovery of facial nerve function, and
- Members have exposed cornea and inadequate lacrimation, and
- Members have failed conservative treatment (e.g., corneal lubricants, moisture chambers, or taping of lower eyelid).

Aetna considers gold-weight or platinum-weight eyelid implants, or palpebral springs experimental and investigational for all other indications because their effectiveness for indications other than the one listed above has not been established.

Aetna considers the following procedures medically necessary for chronic severe paralytic lagophthalmos associated with facial paralysis when there is no reasonable likelihood of spontaneous return of function as determined by electromyography or electroneuronography:

- Muscle transposition surgery (including silicone sling assisted temporalis muscle transfer)
- Neuroplastic surgery (e.g., cross-facial nerve grafting, nerve anastomoses).

Aetna considers the following procedures experimental and investigation for the treatment of paralytic lagophthalmos (not an all-inclusive list):

- Autogenic auricular cartilage grafts in conjunction with lateral canthopexy
- Botulinum toxin (CPB 0113 - Botulinum Toxin)
- Hyaluronic acid.

Background

Paralytic lagophthalmos describes incomplete closure of the eyelids as a result of paralysis of the seventh cranial nerve, usually from lesions affecting the nuclear or peripheral portion of the nerve. Facial paralysis with resultant paralytic lagophthalmos and ectropion can occur from many causes, including Bell's palsy, tumors, trauma, injury, or vascular accidents affecting the facial nerve. There is significant variability in the onset and extent of facial nerve regeneration. The degree of recovery of facial nerve function after paralysis is influenced by the cause of the palsy, the degree of neural injury,
the age of the patient, and the clinical setting. Whatever the cause, the ocular complications of inadequately or improperly managed facial paralysis range in severity from corneal irritation and punctuate keratopathy to corneal ulceration, perforation, and blindness.

Traditional medical therapy has included emollient ointments and eye drops, as well as taping and pressure patches. However, these are of short-lasting benefit and the frequency of application is such that these measures are often abandoned by the patients. This has led to use of surgical procedures in the management of facial paralysis.

Tarsorrhaphy has been the usual palliative treatment of facial paralysis. However, it has many limitations: it does not improve active eyelid closure, it restricts peripheral vision, and it is cosmetically displeasing. Various prosthetic devices have been used to improve lagophthalmos. These techniques often require surgical revision, and have been associated with infection and extrusion.

Gold-weight implantation in the upper lid and surgery to tighten the lower eyelid are now routine procedures for the restoration of function and cosmesis to the paralyzed eyelids. They are simply performed and have been shown to offer consistently satisfactory results. The literature indicates that gold weights have several advantages: (i) they are maintenance free, (ii) implantation can be performed under local anesthesia, (iii) inflammatory reactions are uncommon, (iv) the procedure is reversible without leaving any defects, (v) implantation can be combined with other surgical techniques (such as a lower lid tightening procedure) to obtain maximum corneal protection (marginal entropion, lower lid ectropion repair, and medial canthoplasty can be performed concomitantly, (vi) ocular cosmesis is successfully obtained, and (vii) gold is an inert metal that allows MRI scans if necessary.

Terzis and Kyere (2008a) stated that the loss of the blink reflex and the ability to close the eye actively are disabling functional and aesthetic impairments common to patients with facial paralysis. Non-physiological (static) management techniques involve implantation of devices in the upper eyelid that mechanically aid eye closure. The most popular devices are the gold-weight and the palpebral spring. The authors presented their experience with these devices. A total of 39 patients treated for paralytic lagophthalmos met the inclusion criteria -- 18 received the gold-weight and 21 received the palpebral spring. From standardized video records, pre-operative and post-operative blink scores were calculated. Fifty-nine percent of the patients (23 of 39) were female, and the most common cause for facial paralysis [35.9 % (14 of 39)] was extirpation of acoustic neuroma and other cerebellopontine lesions. Fifty percent of the gold-weight cohort was younger than 20 years at the time of surgery, with almost 40 % (7 of 18) younger than 10 years. In the palpebral spring group, 14.3 % (3 of 21) were younger than 20 years, with 4.8 % (1 of 21) younger than 10 years. The palpebral spring group obtained a larger post-operative mean blink score of 34.0 +/- 12.4 % compared with the gain of 21.4 +/- 14.6 % (p = 0.025) by the gold-weight group. The authors concluded that the gold-weight and palpebral spring are both effective in restoring motion to the paretic upper eyelid, but the palpebral spring is more so despite the frequent need for revisions.

Terzis and Kyere (2008b) also presented their experience with the mini-tendon graft (a piece of split palmaris tendon graft) for lower eyelid suspension. They reported that the mini-tendon graft is an effective technique for re-positioning the paralyzed lower eyelid regardless of patient age, denervation time, or cause of injury, and may be effectively combined with the eye spring or gold-weight in the presence of lagophthalmos.

Bergeron and Moe (2008) stated that the initial treatment of upper eyelid paralysis is supportive, with surgery reserved for those patients that fall into 2 categories: (i) those who have failed non-surgical treatment to protect the cornea, and (ii) those who have been treated effectively with conservative measures but are faced with the prospect of long-term or permanent paralysis. There are a variety of surgical procedures that may be classified as either static or dynamic. Standard static procedures include lid loading and tarsorrhaphy, whereas the palpebral spring implant and the temporalis muscle transfer are classified as dynamic. The goal of the corrective procedures is to allow complete eye closure, thereby providing corneal protection, with minimal (1 mm or less) ptosis in the open position.
Schrom et al (2009) evaluated subjective patient satisfaction following implantation of different eyelid implants. Questionnaires were sent to 42 patients treated by pre-tarsal implantation of a gold-weight (group 1) and 51 patients with a pre-tarsally fixed platinum chain (group 2). In total, 46 response sheets were evaluated (16 x gold-weight, 30 x platinum chain) and the results were compared. In group 1, 75 % of patients were very satisfied to satisfied with the overall result. In group 2, 100 % of patients were very satisfied to satisfied with the overall result. In group 1, an infection occurred in 6.5 % of patients, an extrusion in 6.5 %, and a change of vision in 31 %. In group 2, inflammation occurred in 13 %, extrusion in 0 %, and a change of vision occurred in 13 % of patients. On a visual analog scale from 1 to 10 (1, very good; 10, very poor), group 1 assessed the cosmetic result with an average grade of 3.8 and the functional result with an average grade of 3.1. Group 2 assessed the cosmetic result with the grade 2.9 and the functional result with grade 3.0. The implantation of an eyelid weight for treatment of paralytic lagophthalmos was assessed as positive by a majority of patients. When compared with conventional gold implants, patients who have been treated with a flexible platinum chain are overall more satisfied and have a more favorable subjective view of the cosmetic results.

Silver et al (2009) noted that the gold eyelid weight, introduced nearly 50 years ago, continues to enjoy immense popularity, despite high complication rates and nearly uniform visibility under the skin. The authors hypothesized that a commercially available, thin platinum-weight would combat the visibility of the thicker gold-weights and herein compared complication rates and visibility rates with literature-reported data for gold-weights. Beginning in 2004, 100 consecutive patients presenting to the authors' Facial Nerve Center with paralytic lagophthalmos requiring intervention were treated with thin-profile platinum eyelid weights. Ninety-six percent of cases were performed under local anesthesia in the office setting. Median follow-up was 22 months. In 102 weights placed, there have been 6 complications (5.9 %): 3 extrusions, 2 capsule formations, and 1 case of astigmatism. All of the extrusions involved irradiated patients with parotid malignancies. The authors concluded that this study was the first large series of thin-profile platinum eyelid weight implantations for the treatment of lagophthalmos. This implant significantly reduces both capsule formation phenomena and extrusion compared with gold-weights and should be considered as alternative to the more conventional gold-implants.

In a retrospective interventional case series, Taban et al (2009) reported their preliminary experience using hyaluronic acid (HA) gel fillers as a non-surgical alternative in the management of congenital eyelid malpositions. A total of 5 patients (10 eyes) with congenital eyelid malpositions, including eyelid retraction, ectropion, euryblepharon, epiblepharon, and abnormalities associated with a shallow orbit, with resultant lagophthalmos and/or keratopathy and tearing were evaluated before and after injection with HA gel (Restylane) in the pre-tarsal and/or septal regions of the affected eyelid(s). Pre-treatment, post-treatment, and follow-up photographs were analyzed for eyelid position and degree of eyelid closure and lagophthalmos, and slit-lamp evaluation of the degree of keratopathy. All 5 patients demonstrated significant improvement of eyelid position and degree of keratopathy. The mean improvement in lagophthalmos was 4.5 mm (range of 2 to 7 mm). The average volume of HA gel used was 0.5 ml per eyelid. Complications were minor, including transient edema and ecchymosis at the sites of injection. Of the 10 eyelids injected, only 1 had increased astigmatism after injection. The authors concluded that HA gel shows promise as a safe and effective non-surgical treatment for the management of certain eyelid malpositions, disorders traditionally requiring surgical intervention if aggressive ocular lubrication fails.

Grusha and associates (2010) reported their first experience in using the stabilized HA preparation in patients with lagophthalmos in the presence of facial nerve palsy and thyroid eye disease and resultant keratopathy of varying degrees. A total of 21 patients, including 15 patients with facial nerve palsy and 6 with endocrine ophthalmopathy were included in this study. The gel was injected externally to the levator aponeurosis and/or intramuscular, and/or under the pre-tarsal portion of the orbicularis oculi muscle, and/or subcutaneously. The use of this method led to a significant reduction of lagophthalmos and to a considerable corneal improvement. This procedure also permitted avoidance of surgical intervention in some patients. The mean follow-up period after injection was 11.2 months (range of 6 to 24 months).
In a review on surgical treatment options for paralytic lagophthalmos (no authors listed, 2010), it was noted that facial nerve palsy may result from a broad spectrum of causes, which is largely due to its topographic complexity. Different types of cross plastic surgery and nerve autografting and muscle transplantation and transposition are used to recover nerve function. Lagophthalmos is a most severe sequel of facial nerve palsy. Blephorrhaphy and tarsorrhaphy, operations for removal of lower eyelid ectropion, and different types of palpebral fissure narrowing are used widely to correct lagophthalmos and to prevent corneal complications. Various weight implants and special springs are employed to modify upper eyelid mobility. The lengthening of the upper eyelid levator and the administration of botulotoxin type A and hyaluronic acid gel are proposed for additional upper eyelid descent. The clinical value of these procedures needs to be validated by well-designed studies.

In a retrospective study, Martín-Oviedo et al (2013) evaluated the safety and effectiveness of injecting hyaluronic acid gel into the upper eyelid as a non-surgical alternative for patients with temporary facial palsy. A total of 26 patients were treated with hyaluronic acid gel injected into the pre-tarsal region of the upper eyelid. Measurements taken before and after treatment were standardized and compared using digitized photographs. Patients were followed-up for 1 year, and overall outcomes were assessed. All patients initially demonstrated improvement in lagophthalmos, which decreased to 0.0 mm. After 1 month, a significant increase in lagophthalmos was observed in 2 patients (initial fissure of 8 and 9 mm), and a platinum weight was implanted to control keratopathy. The remaining patients (initial lagophthalmos below 6.5 mm) maintained the improvement until facial restoration. Only 3 patients had recurrent lagophthalmos (2 mm) due to resorption, which was resolved by injecting an additional 0.3 cc. The mean improvement in lagophthalmos was 4.6 mm (range of 3.5 to 6.5 mm). Complications included transient ecchymosis and minimal blepharoptosis due to non-reabsorption in 5 patients. These patients were successfully treated with hyaluronidase. The authors concluded that the hyaluronic acid gel has proven effective in reducing paralytic lagophthalmos and controlling keratopathy in patients with temporary facial palsy, especially those with palpebral fissure with attempted closure no greater than 6.5 mm. Injection of hyaluronic acid gel is safe, quick, and easily performed. Furthermore, it is more cost-effective than surgery. The level of evidence for this study was “IV”; the findings of this small retrospective study need to be validated by well-designed studies.

Friedhofer et al (2013) analyzed the use of autogenic auricular cartilage grafts as weight for the upper eyelid in conjunction with lateral canthopexy for patients with mild paralytic lagophthalmos. This procedure was also accompanied by elevation of the lower eyelid using the cartilage graft for moderate cases. These investigators conducted a retrospective study including case series of 30 patients with paralytic lagophthalmos from 1997 to 2010. For mild cases, cartilage from the auricular scapha was placed in pre-tarsal space of the upper eyelid and cartilage from the concha was inserted in pre-aponeurotic space and then sutured to the levator aponeurosis in conjunction with lateral canthopexy. For moderate cases, lower eyelid was also elevated by suturing cartilage graft to tarsum and resting it by the inferior orbital rim. All patients had some degree of keratopathy before the intervention. After treatment, they presented with evident clinical improvement, reduction of eye symptoms, and resolution of keratopathy. During post-operative follow-up (mean of 37.3 months), none of the patients exhibited cartilage graft exposition, reabsorption, visibility, infection, or warping. Complete eye closure was achieved in 24 (80 %) patients, whereas the remaining 6 (20 %) patients had residual asymptomatic lagophthalmos. The authors concluded that the intervention using autogenic auricular cartilage grafts was only effective for the treatment of mild and moderate cases of paralytic lagophthalmos. This out-patient surgery was associated with low morbidity and achievement of functional and aesthetic improvement. The findings of this small retrospective study need to be validated by well-designed studies.

In a prospective interventional study, Gupta et al (2014) evaluated the effectiveness of modified temporalis muscle transfer (TMT) by silicone sling for the management of paralytic lagophthalmos. A total of 10 patients of lagophthalmos due to facial palsy underwent modified TMT using silicone sling. Patients were followed-up for a period of 3 months. Palpebral aperture in primary gaze and during eye closure were assessed both pre- and post-operatively along with problems associated with
lagophthalmos like exposure keratopathy and lacrimation. Paired t-test was applied to measure the statistical outcome. A total of 8 patients achieved full correction of lagophthalmos with no lid gap on closing the eye. The mean (standard deviation (SD)) lid gap on eye closure was 7.7 (0.86) mm pre-operatively, 0.5 (0.47) mm at 1st post-operative day, and 0.7 (0.75) mm at 3rd month. There was a reduction in mean lid gap on eye closure of 7 mm at 3 months (p < 0.0001) that was highly significant. The mean (SD) vertical inter-palpebral distance during primary gaze was 12.05 (1.12) mm pre-operatively, 10 (0.94) mm at 1st post-operative day, and 10.35 (1.08) mm at 3rd month. There was a reduction in mean vertical inter palpebral distance of 1.7 mm at 3 months (P = 0.001) which is significant. Exposure keratitis decreased in 5 out of 6 patients at 3 months. The authors concluded that modified TMT by silicone sling is a useful procedure with lesser morbidity and good outcomes for the treatment of paralytic lagophthalmos due to long standing facial palsy. These preliminary findings need to be validated by well-designed studies with larger sample size and longer follow-up.

Muscle Transposition Surgery and Neuroplastic Surgery:

Iskusnykh and Grusha (2015) stated that various procedures are used for the permanent correction of paralytic lagophthalmos (e.g., upper eyelid weights or spring implantation). These investigators noted that muscle transposition surgery and neuroplastic surgery (e.g., cross-facial nerve grafting, nerve anastomoses) are not effective enough. The majority of elderly and medically compromised patients should not be considered for such complicated and long procedures. The authors concluded that upper eyelid weight implantation appeared the most reliable and simple treatment.

**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

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

- 64864  Suture of facial nerve; extracranial [for treatment of paralytic lagophthalmos]
- 64865  Suture of facial nerve; infratemporal, with or without grafting [for treatment of paralytic lagophthalmos]
- 64885  Nerve graft (includes obtaining graft), head or neck; up to 4 cm in length
- 64886  Nerve graft (includes obtaining graft), head or neck; more than 4 cm length
- +69401  Nerve graft, each additional nerve; single strand (List separately in addition to code for primary procedure)
- +69402  Nerve graft, each additional nerve; multiple strands (cable) (List separately in addition to code for primary procedure)
- +67320  Transposition procedure (eg, for paretic extraocular muscle), any extraocular muscle (specify) [for treatment of paralytic lagophthalmos]
- 67912  Correction of lagophthalmos, with implantation of upper eyelid lid load (e.g., gold weight)

**CPT codes not covered for indications in the CPB:**

*Silicone sling assisted temporalis muscle transfer - no specific code:*

- 15760  Graft; composite (eg, full thickness of external ear or nasal ala), including
The above policy is based on the following references:


Amendment to
Aetna Clinical Policy Bulletin Number: 0366 Paralytic Lagophthalmos Treatments

There are no amendments for Medicaid.