Clinical Policy Bulletin: Bell's Palsy

Number: 0745

Policy

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

I. Aetna considers blink reflex testing medically necessary for the diagnosis of Bell's palsy (see CPB 0502 - Nerve Conduction Studies).

II. Aetna considers measurement of blood levels of total and native thiol and disulphide activity experimental and investigational as a pathogenetic marker of Bell's palsy because the clinical value of this approach has not been established.

III. Aetna considers neuromuscular ultrasound experimental and investigational for the diagnosis of Bell's palsy because its clinical value has not been established.

IV. Aetna considers the use of gold weight eyelid implants medically necessary for the treatment of Bell's palsy (see CPB 0366 - Paralytic Lagophthalmos: Treatments).

V. Aetna considers facial surgery including anastomosis with branches of other cranial nerves, fascia slings, muscle transposition, or other procedures of the facial nerve (e.g., cross facial nerve grafting using sural nerve followed by microvascular muscle transfer) medically necessary for the treatment of chronic facial paralysis due to Bell's palsy or other conditions if all of the following criteria are met:

A. Facial paralysis has persisted for more than 12 months; and
B. Facial paralysis has resulted in impaired functional deficit in mastication, speech, or vision; and
C. There is no reasonable likelihood of spontaneous return of function as determined by electromyography or electroneuronography.

VI. Aetna considers any of the following treatments for Bell's palsy experimental and investigational because their effectiveness for this indication has not been established:

- Acupuncture (see CPB 0135 - Acupuncture)
- Anti-viral therapy
- Botulinum toxin (see CPB 0113 - Botulinum Toxin)
- Electrical stimulation (see CPB 0011 - Electrical Stimulation for Pain)
- Facial nerve decompression
- Facial retraining therapy
- Hyperbaric oxygen therapy (see CPB 0172 - Hyperbaric Oxygen Therapy (HBOT))
- Infrared therapy (see CPB 0604 - Infrared Therapy)
- Intra-tympanic steroid injection
Background

Bell's palsy, also known as acute idiopathic facial paresis, is an idiopathic neuropathy of the facial nerve (cranial nerve VII). It is a rapid onset facial paralysis that is not life-threatening. While acute immune demyelination triggered by a viral infection may be responsible for Bell's palsy, its exact cause is still unclear. Bell's palsy is usually self-limiting with the majority of patients recovering spontaneously without treatment within 6 months of onset of the disorder. However, a recent study by Kanazawa et al (2007) reported that recovery from Bell's palsy in diabetics is delayed, and the facial movement score remains low in comparison with non-diabetics.

The diagnosis of Bell's palsy is primarily one of exclusion, however certain features in the history and physical examination can aid in distinguishing it from facial paralysis as a consequence of other conditions. These clinical features include abrupt onset with complete, unilateral facial weakness at 24 to 72 hours, and, on the affected side, numbness or pain around the ear, a reduction in taste, and hypersensitivity to sounds (Ahmed, 2005).

Blink reflex testing and facial electromyography (EMG) have been used in the diagnosis of patients with Bell's palsy. Hill et al (2001) investigated electrophysiologically a population-based sample of patients with Bell's palsy to help understand the spectrum of abnormalities that can be seen in this setting. A total of 224 patients were surveyed, of whom 91 underwent formal neurological assessment. Of the latter, 44 were studied electrophysiologically using standard techniques. Thirty-two of the 44 patients fulfilled clinical criteria for Bell's palsy. A wide range of electrophysiological changes was observed. Blink responses were the most useful test showing diagnostic sensitivity of 81% and specificity of 94% compared to the contralateral control side. Needle EMG was additionally helpful in only 1 of 6 patients with normal conduction studies. The authors concluded that there is a wide spectrum of electrophysiological abnormalities in Bell's palsy. They stated that blink reflex latencies may be under-utilized in the assessment of the facial nerve in Bell's palsy; and facial EMG is generally not useful in routine evaluation. In an analysis of the clinical value of blink reflex, Xu et al (2007) noted that as one convenient test, blink reflex helps locate the lesion of trigeminal nerve or facial nerve and has highly diagnostic value to the lesion of brain stem, even to the subclinical lesion at the early time of some disease without any symptoms.

Transcranial magnetic stimulation (TMS) has been employed in the diagnosis of Bell's palsy. Recently, Nowak and colleagues (2005) noted that earlier investigations have suggested that isolated conduction block of the facial nerve to TMS early in the disorder represents a very sensitive and potentially specific finding in Bell's palsy differentiating the disease from other etiologies. These researchers examined the diagnostic relevance of TMS and electrical stimulation (ES) of the facial nerve in the management of facial/Bell's palsy. Stimulation of the facial nerve was performed electrically at the stylomastoid foramen and magnetically at the labyrinthine segment of the Fallopian channel within 3 days from symptom onset in 65 patients with Bell's palsy, 5 patients with Zoster oticus, 1 patient with neuroborreliosis, and 1 patient with nuclear facial nerve palsy due to multiple sclerosis. Absence or decreased amplitudes of muscle responses to early TMS was not specific for Bell's palsy, but also evident in all cases of Zoster oticus and in the case of neuroborreliosis. Amplitudes of electrically evoked muscle responses were more markedly reduced in Zoster oticus as compared to Bell's palsy, most likely due to a more severe degree of axonal degeneration. The degree of amplitude reduction of the muscle response to ES reliably correlated with the severity of facial palsy. The authors concluded...
that TMS in the early diagnosis of Bell's palsy is less specific than previously thought.

Bell's palsy has a generally favorable prognosis. Jabor and Gianoli (1996) stated that 84% of patients reported satisfactory recovery without any treatment, however 16% suffered moderate to severe sequelae. Prognosis was influenced by degree of paresis, age of patient, and time until first signs of recovery. On the other hand, in a study that assessed the prognostic factors in patients with Bell's palsy (n = 55) and Ramsay Hunt syndrome (n = 26), Yeo et al (2007) reported that there was no prognostic factor found in the Bell's palsy patients; while prognostic factors of Ramsay Hunt syndrome were age, diabetes mellitus, essential hypertension as well as vertigo.

Treatment of Bell's palsy is still not well-defined. Conservative approaches entail physiotherapies such as facial exercises, massage, and muscle relaxation, which may support rehabilitation and possibly reduce the production of pathological synkinesia. Medical treatments include anti-viral agents, botulinum toxin type A (Botox), cortisone and possibly antibiotics. However, the effectiveness of some of these therapies has not been established. The American Academy of Neurology's practice parameters on Bell's palsy (Grogan and Gronseth, 2001) stated that for patients with Bell's palsy, a benefit from steroids, acyclovir, or facial nerve decompression has not been definitively established. However, available evidence suggests that steroids are probably effective and acyclovir (combined with prednisone) is possibly effective in improving facial functional outcomes.

The American Academy of Neurology practice parameters on Bell's palsy (Grogan and Gronseth, 2001) found insufficient evidence to make recommendations regarding surgical facial nerve decompression for Bell's palsy. The guidelines stated that well-designed studies of the effectiveness of treatments for Bell's palsy are still needed. A systematic evidence review in BMJ Clinical Evidence concluded that the effect of facial nerve decompression in adults and children with Bell's palsy is unknown (Holland, 2007).

Chepeha and associates (2001) found that in patients with facial paralysis, gold weight eyelid implants provided significant reduction in lagophthalmos and significant improvement in corneal coverage. This is in agreement with the findings of Abell et al (1998) as well as Choi et al (1999). Abell and colleagues (1998) noted that deficient eyelid closure is a major visual threat to patients with unresolved facial nerve palsy. Gold weight implants aided eyelid closure in patients with paresis of the orbicularis oculi, ameliorating patient complaints of dry eye, excessive tearing, and corneal epithelial breakdown. Choi and co-workers (1999) reported that in patients with complete facial nerve palsy, implantation of gold weight resulted in dynamic closure of the eyelid as well as excellent protection and cosmesis. These researchers also noted that lagophthalmos and exposure keratitis resolved in treated patients; and visual acuity significantly improved without complications.

Acupuncture, ES, and hyperbaric oxygen therapy have also been used in treating Bell's palsy. However, the effectiveness of these modalities has not been established. Although a recent study (Liang et al, 2006) reported that acupuncture and moxibustion may exert therapeutic effects on Bell's palsy, better than that of the basic treatment group (i.e., prednisone, vitamin B1, vitamin B12, and dibazol) or the basic treatment plus acupuncture-moxibustion group, a Cochrane review (He et al, 2007) stated that more evidence is needed to show whether acupuncture is beneficial for Bell's palsy. Zhou and colleagues (2009) examined the effectiveness of acupuncture in hastening recovery and reducing long-term morbidity from Bell's palsy. These investigators concluded that the quality of the included trials was inadequate to allow any conclusion regarding the effectiveness of acupuncture. They stated that further investigation with high-quality trials is needed.

Adour (1991) noted that facial nerve decompression and electrotherapy are not advised for the management of patients with Bell's palsy. This is in agreement with Wolf (1998) who stated that ES should not be used in the treatment of Bell's palsy. Diels (2000) stated that ES should not be used at any time in facial rehabilitation. There is evidence that it may be contraindicated, and it is unnecessary. Buttress and Herren (2002) reviewed the medical literature to ascertain whether ES had any advantages over facial exercises in promoting recovery after Bell's palsy. Of the 270 papers found
using the reported search, only 1 presented the best evidence to answer the clinical question. The authors stated that there is no evidence to suggest that either facial exercises or ES is beneficial to patients with acute Bell's palsy. However, evidence does exist to justify the use of ES in patients with chronic Bell's palsy, although the study design was not rigorous. An evidence review conducted by the Alberta Heritage Foundation for Medical Research (Hailey, 2003) concluded that use of hyperbaric oxygen therapy is not supported for a number of conditions including Bell's palsy.

It has been suggested that some patients with Bell's palsy may benefit from a special form of physical therapy called facial retraining, which entails a specific program designed to retrain facial muscles for movement and expression following facial nerve paralysis. The objectives of facial retraining therapy are:

I. to normalize movement of facial muscles,
II. to increase symmetrical movement patterns of the face,
III. to increase volitional movements of the face,
IV. to inhibit undesired movements and synkinesis, and
V. to normalize muscular tone.

Facial retraining involves a thorough evaluation of facial movements through observation, dual channel EMG and sensation. This regimen includes active self training by patients (e.g., specific functional facial exercises), EMG training by means of sensory, visual and auditory feedback as well as supervised sessions that incorporate the use of modalities such as ES, heat/cold and massage.

Brach et al (1997) described the outcome of facial neuromuscular retraining for oral synkinesis in individuals with facial nerve disorders (n = 14). These researchers concluded that brow to oral as well as ocular to oral synkineses associated with partial recovery from facial paralysis were reduced with facial neuromuscular retraining. Diels (2000) stated that patients with facial paralysis resulting from viral causes, post-surgical tumor resection, traumatic injury, or congenital paresis may be candidates for treatment. Typical patients present with flaccid paralysis acutely and may develop abnormal movement patterns (synkinesis) as recovery progresses. Neuromuscular retraining provides specific strategies that inhibit synkinesis based on individual function and unique facial nerve and muscle properties. Cronin et al (2003) found that neuromuscular facial retraining exercises and EMG are effective for improving facial movements (n = 24). While there is preliminary evidence that facial retraining may be effective for patients with facial paralysis, it must be noted that these studies were small and none of them was a controlled trial. The value of facial retraining for patients with Bell's palsy awaits findings from randomized controlled studies.

Cederwall et al (2006) evaluated a physiotherapeutic treatment intervention in Bell's palsy. A consecutive series of 9 patients with Bell's palsy participated in the study. Participants were enrolled 4 to 21 weeks after the onset of facial paralysis. The study had a single subject experimental design with a baseline period of 2 to 6 weeks and a treatment period of 26 to 42 weeks. Subjects were evaluated using a facial grading score, a paresis index and a written questionnaire created for this study. Every patient was taught to perform an exercise program twice-daily, including movements of the muscles surrounding the mouth, nose, eyes and forehead. All patients improved in terms of symmetry at rest, movement and function. The authors concluded that patients with remaining symptoms of Bell's palsy appear to experience positive effects from a specific training program. Moreover, these investigators noted that a larger study is needed to fully evaluate the treatment.

Cardoso et al (2008) examined the effects of facial exercises associated either with mirror or EMG biofeedback with respect to complications of delayed recovery in Bell's palsy. Patients with unilateral idiopathic facial palsy were included in this review. Main outcome measures were report of facial symmetry, synkinesis, lip mobility, and physical and social aspects. Four studies met the eligibility criteria. The studies described mime therapy versus control (n = 50), mirror biofeedback exercise versus control (n = 27), "small" mirror movements versus conventional neuromuscular retraining (n = 10), and EMG biofeedback plus mirror training versus mirror training alone. The duration of treatment
varied from 1 to 12 months. The authors concluded that because of the small number of randomized controlled trials (RCTs), it was impossible to analyze if facial exercises, associated either with mirror or EMG biofeedback, were effective. They stated that the available evidence is not yet strong enough to allow facial exercises (with mirror or EMG biofeedback) to be integrated into clinical practice.

Osteopathic and chiropractic manipulation has also been used to treat Bell's palsy (Alcantara et al, 2003; Lancaster and Crow, 2006). However, there is insufficient scientific evidence to support their effectiveness for this indication.

Although corticosteroids and anti-viral therapy given within 10 days of onset have been reported to help, there is still controversy regarding these therapies.

A Cochrane review (Salinas et al, 2004) stated that available evidence from RCTs does not demonstrate significant benefit of corticosteroids in treating patients with Bell's palsy. These investigators further stated that more RCTs with a greater number of patients are needed to determine reliably whether there is real benefit (or harm) from the use of corticosteroid therapy in patients with Bell's palsy. Another Cochrane review (Allen and Dunn, 2004) concluded that more data are needed from a large multi-center randomized controlled and blinded trial with at least 12 months' follow-up before a definitive recommendation can be made regarding the effectiveness of acyclovir or valacyclovir on Bell's palsy. Furthermore, Gilden (2004) noted that large randomized double-blind studies are needed to better ascertain the effectiveness of glucocorticoids, anti-viral agents, or both as compared with placebo, as well as to evaluate the benefit of surgical decompression among patients considered to be at high risk for permanent paralysis. In particular, studies are needed to determine the time after which medical therapy or surgery is of no value. Additionally, more investigation is needed to examine if a combination of anti-viral and corticosteroid therapy is more effective than treatment with corticosteroids alone. In a review of treatment of Bell's palsy using anti-viral agents, Alberton and Zed (2006) stated that the use of acyclovir remains controversial. These investigators noted that additional, adequately powered, randomized, placebo-controlled studies are needed to definitively support its use. For the time being, the authors favor the combination of acyclovir and prednisone only if treatment is commenced within the first 72 hours of symptom onset.

Turk-Boru et al (2005) stated that although corticosteroid therapy is widely used in patients with idiopathic facial nerve paralysis, its effectiveness has not been clearly demonstrated. In an open, randomized, prospective controlled study (n = 56), these researchers assessed the role of steroids in idiopathic facial nerve paralysis. Within the first three days after the onset of symptoms, the patients were randomly assigned to two groups to receive either steroids or other medications for the prevention of ocular complications or to provide pain relief. The severity of facial paralysis was evaluated using the House-Brackmann classification before and after 3 and 6 weeks of the treatment. Regression to stage 1 or 2 disease was regarded as a successful response. Although the initial response to steroid therapy seemed to be better, the results at the end of 3 and 6 weeks of the treatment were not statistically different from those of patients receiving other supportive treatments (p > 0.05). The authors concluded that more studies with large patient series are needed to clarify the use of steroids in the treatment of idiopathic facial nerve paralysis. Atzema and Goldman (2006) stated that the best available evidence shows no benefit from steroids in the treatment of children with Bell's palsy; they noted that until a large, randomized, controlled study can prove otherwise, these patients should not be treated with steroids. Rahman and Sadiq (2007) stated that the use of steroids has been suggested as a means of limiting facial nerve damage in the acute phase of facial nerve palsy. Unfortunately, no single randomized control trial has achieved an unquestionable benefit with the use of oral steroid therapy; thus its use remains controversial.

In a multi-center, randomized placebo-controlled study, Hato et al (2007) examined the effects of valacyclovir and prednisolone in comparison with those of placebo and prednisolone for the treatment of Bell's palsy, excluding zoster sine herpete. A total of 221 patients with Bell's palsy were treated within 7 days of the onset. Serological and polymerase chain reaction examinations were performed to distinguish Bell's palsy from zoster sine herpete. Patients were treated with either valacyclovir
(dosage, 1,000 mg/d for 5 days) plus prednisolone (VP [n = 114]) or placebo plus prednisolone (PP [n = 107]) administered orally. Recovery from Bell's palsy was defined as a score higher than 36 using Yanagihara 40-point scoring system without facial contracture or synkinesis. Patients were followed-up until complete recovery occurred or for more than 6 months in cases with a poor prognosis. The overall rate of patient recovery among those treated with VP (96.5 %) was significantly better (p < 0.05) than the rate among those treated with PP (89.7 %). The rate of patient recovery was also analyzed by classifying the initial severity of facial palsy. In cases of complete or severe palsy, the rates of patients treated with VP and PP who recovered were 95.7 % (n = 92) and 86.6 % (n = 82), respectively; the recovery rate for treatment with VP was significantly better than that with PP (p < 0.05). The authors concluded that the valacyclovir and prednisolone therapy was more effective in treating Bell's palsy, excluding zoster sine herpete, than the conventional prednisolone therapy.

Although treatment with valacyclovir and prednisolone was found to be significantly (statistically) better than prednisolone alone (97 % versus 90 %), it is unclear whether this difference is clinically significant. These findings need to be validated by further investigation.

The Health Technology Assessment Program of the National Institute for Health Research commissioned an independent academic group to determine if prednisolone or acyclovir used early in the course of Bell's palsy improves the chances of recovery. Sullivan et al (2007) performed a double-blind, placebo-controlled, randomized, factorial study involving patients with Bell's palsy who were recruited within 72 hours after the onset of symptoms. Patients were randomly assigned to receive 10 days of treatment with prednisolone, acyclovir, both agents, or placebo. The primary outcome was recovery of facial function, as rated on the House–Brackmann scale; secondary outcomes included quality of life, appearance, and pain. Final outcomes were assessed for 496 of 551 patients who underwent randomization. At 3 months, the proportions of patients who had recovered facial function were 83.0 % in the prednisolone group as compared with 63.6 % among patients who did not receive prednisolone (p < 0.001) and 71.2 % in the acyclovir group as compared with 75.7 % among patients who did not receive acyclovir (adjusted p = 0.50). After 9 months, these proportions were 94.4 % for prednisolone and 81.6 % for no prednisolone (p < 0.001) and 85.4 % for acyclovir and 90.8 % for no acyclovir (adjusted p = 0.10). For patients treated with both drugs, the proportions were 79.7 % at 3 months (p < 0.001) and 92.7 % at 9 months (p < 0.001). There were no clinically significant differences between the treatment groups in secondary outcomes. There were no serious adverse events in any group. The authors concluded that in patients with Bell's palsy, early treatment with prednisolone significantly improves the chances of complete recovery at 3 and 9 months. There is no evidence of a benefit of acyclovir given alone or an additional benefit of acyclovir in combination with prednisolone.

While the study by Hato et al (2007) suggested that valacyclovir may be a useful addition to prednisolone, it was smaller than the afore-mentioned study by Sullivan and colleagues. Furthermore, as pointed out by Sullivan et al, patients in the study by Hato et al were treated in tertiary centers, and the outcome assessors were aware of the study-group assignments. Thus, the results of that study should be interpreted with caution.

de Almeida and colleagues (2009) estimated the association of corticosteroids and anti-viral agents with the risk of unsatisfactory facial recovery in patients with Bell palsy. Eligible studies were RCTs comparing treatment with either corticosteroids or anti-viral agents with a control and measuring at least 1 of the following outcomes: unsatisfactory facial recovery (greater than or equal to 4 months), unsatisfactory short-term recovery (6 weeks to less than 4 months), synkinesis and autonomic dysfunction, or adverse effects. Two reviewers extracted data on study characteristics, methods, and outcomes. Disagreement was resolved by consensus. A total of 18 trials involving 2786 patients were eligible. Regression analysis identified a synergistic effect when corticosteroids and anti-viral agents were administered in combination compared with alone (odds ratio for interaction term, 0.54 [95 % confidence interval (CI): 0.35 to 0.83]; p = 0.004). Meta-analysis using a random-effects model showed corticosteroids alone were associated with a reduced risk of unsatisfactory recovery (relative risk [RR], 0.69 [95 % CI: 0.55 to 0.87]; p = 0.001) (number needed to treat to benefit 1 person, 11 [95 % CI: 8 to 25]), a reduced risk of synkinesis and autonomic dysfunction (RR, 0.48 [95 % CI: 0.36 to 0.65]; p < 0.001) (number needed to treat to benefit 1 person, 7 [95 % CI: 6 to 10]), and no increase in
adverse effects. Anti-viral agents alone were not associated with a reduced risk of unsatisfactory recovery (RR, 1.14 [95 % CI: 0.80 to 1.62]; p = 0.48). When combined with anti-viral agents, corticosteroids were associated with greater benefit (RR, 0.48 [95 % CI: 0.29 to 0.79]; p = 0.004) than anti-viral agents alone. When combined with corticosteroids, anti-viral agents were associated with greater risk reduction of borderline significance compared with corticosteroids alone (RR, 0.75 [95 % CI: 0.56 to 1.00]; p = 0.05). The authors concluded that in Bell palsy, corticosteroids are associated with a reduced risk of unsatisfactory recovery. Anti-viral agents, when administered with corticosteroids, may be associated with additional benefit.

On the other hand, in a systematic review and meta-analysis of corticosteroids versus corticosteroids plus anti-viral agents in the treatment of Bell palsy, Goudakos and Markou (2009) found that the addition of an anti-viral agent to corticosteroids for the treatment of Bell palsy is not associated with an increase in the complete recovery rate of the facial motor function. Prospective RCTs on the treatment of patients with Bell palsy were selected for this analysis. Odds ratios (ORs), 95 % CIs, and tests for heterogeneity were reported. A total of 5 studies were eventually identified and systematically reviewed. Meta-analysis was performed for 4 studies. Regarding the complete recovery rate of facial nerve paralysis 3 months after initiation of therapy, the current systematic review and meta-analysis suggests that the addition of an anti-viral agent does not provide any benefit (OR, 1.03 [95 % CI: 0.74 to 1.42]; p = 0.88). The same conclusion emerged at posterior (4th, 6th, and 9th) months of assessment. Subgroup analysis, conducted on the basis of time point of therapy initiation, type of anti-viral agent, and blindness of assessments did not change the results obtained. The occurrence rate of adverse effects attributable to therapy choice was not significantly different between patients receiving corticosteroids and those following combined treatment. A systematic evidence review by Quant et al (2009) reached similar conclusions about the lack of proven benefit of antiviral agents in Bell's palsy. The authors concluded that combined treatment using steroids and antivirals compared with steroids alone provided no additional benefit in achieving at least partial facial muscle recovery in patients with Bell's palsy.

In a Cochrane review, Lockhart and colleagues (2009) examined the effect of anti-viral therapy on Bell's palsy. These investigators updated the search of the Cochrane Neuromuscular Disease Group Trials Register (December 2008), MEDLINE (from January 1966 to December 8 2008), EMBASE (from January 1980 to December 8 2008) and LILACS (from January 1982 to December 2008). Randomized trials of anti-virals with and without corticosteroids versus control therapies for the treatment of Bell's palsy. A total of 23 papers were selected for consideration -- 7 trials including 1,987 participants met the inclusion criteria, adding 5 studies to the 2 in the previous review. There was no significant benefit in the rate of incomplete recovery from anti-virals compared with placebo (n = 1,886, RR 0.88, 95 % CI: 0.65 to 1.18). In meta-analyses with some unexplained heterogeneity, the outcome with anti-virals was significantly worse than with corticosteroids (n = 768, RR 2.82, 95 % CI: 1.09 to 7.32) and the outcome with anti-virals plus corticosteroids was significantly better than with placebo (n = 658, RR 0.56, 95 % CI: 0.41 to 0.76). In single trials, there was no significant difference in long-term sequelae comparing anti-virals and corticosteroids with corticosteroids alone (n = 99, RR 0.39, 95 % CI: 0.14 to 1.07) or anti-virals with corticosteroids (n = 101, RR 1.03, 95 % CI: 0.51 to 2.07). There was no significant difference in rates of adverse events between anti-virals and placebo (n = 1544, RR 1.06, 95 % CI: 0.81 to 1.38), between anti-virals and corticosteroids (n = 667, RR 0.96, 95 % CI: 0.65 to 1.41) or between the anti-viral/corticosteroid combination and placebo (n = 658, RR 1.15, 95 % CI: 1.79 to 1.66). The authors concluded that high quality evidence showed no significant benefit from anti-herpes simplex anti-virals compared with placebo in producing complete recovery from Bell's palsy. Moderate quality evidence showed that anti-virals were significantly less likely than corticosteroids to produce complete recovery.

It is also interesting to note that in an economic evaluation of early administration of prednisolone and/or aciclovir for the treatment of Bell's palsy, Hernandez and colleagues (2009) concluded that treatment with prednisolone is likely to be considered cost-effective, while treatment with acyclovir is highly unlikely to be considered cost-effective. They stated that further data on costs and utilities
would be useful to confirm these findings.

Alakram and Puckree (2010) examined the safety and potential effectiveness of applying electrical stimulation to the facial muscles during the early phase of Bell's palsy. A pre-test post-test control versus experimental groups design composed of 16 patients with Bell's palsy of less than 30 days' duration. Adult patients with clinical diagnosis of Bell's palsy were systematically (every second patient) allocated to the control and experimental groups. Each group (n = 8) was pre-tested and post-tested using the House-Brackmann index. Both groups were treated with exercises, heat, massage, and a home program. The experimental group also received electrical stimulation. The House-Brackmann Scale of the control group improved between 17% and 50% with a mean of 30%. The scores of the experimental group ranged between 17% and 75% with a mean of 37%. The difference between the groups was not statistically significant (2-tailed p = 0.36). Electrical stimulation as used in this study during the acute phase of Bell's palsy is safe but may not have added value over spontaneous recovery and multi-modal physiotherapy. The authors stated that a larger sample size or longer stimulation time or both should be investigated.

In a Cochrane review, McAllister and colleagues (2011) evaluated the effectiveness of surgery in the management of Bell's palsy and compared this to outcomes of medical management. These investigators searched the Cochrane Neuromuscular Disease Group Specialized Register (November 23, 2010). They also searched the Cochrane Central Register of Controlled Trials (CENTRAL) (November 23 in The Cochrane Library, Issue 4, 2010). They adapted this strategy to search MEDLINE (January 1966 to November 2010) and EMBASE (January 1980 to November 2010). These researchers included all randomized or quasi-randomized controlled trials involving any surgical intervention for Bell's palsy. Two review authors independently assessed whether trials identified from the search strategy were eligible for inclusion. Two review authors assessed trial quality and extracted data independently. Two trials with a total of 69 participants met the inclusion criteria. The first study considered the treatment of 403 patients but only included 44 in their surgical study. These were randomized into a surgical and non-surgical group. The second study had 25 participants which they randomly allocated into surgical or control groups. The nerves of all the surgical group participants in both studies were decompressed using a retro-auricular approach. The primary outcome was recovery of facial palsy at 12 months. The first study showed that both the operated and non-operated groups had comparable facial nerve recovery at 9 months. This study did not statistically compare the groups but the scores and size of the groups suggested that statistically significant differences are unlikely. The second study reported no statistically significant differences between their operated and control groups. One operated patient in the first study had 20 dB sensorineural hearing loss and persistent vertigo. The authors concluded that there is only very low quality evidence from randomized controlled trials and this is insufficient to decide whether surgical intervention is beneficial or harmful in the management of Bell's palsy. They stated that further research into the role of surgical intervention is unlikely to be performed because spontaneous recovery occurs in most cases.

Teixeira et al (2011) evaluated physical therapies for Bell's palsy. These investigators searched the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials (The Cochrane Library, Issue 1, 2011), MEDLINE (January 1966 to February 2011), EMBASE (January 1946 to February 2011), LILACS (January 1982 to February 2011), PEDro (from 1929 to February 2011), and CINAHL (January 1982 to February 2011). They included searches in clinical trials register databases until February 2011. They selected RCTs or quasi-RCTs involving any physical therapy, and included participants of any age with a diagnosis of Bell's palsy and all degrees of severity. The outcome measures were: incomplete recovery 6 months after randomization, motor synkinesis, crocodile tears or facial spasm 6 months after onset, incomplete recovery after 1 year and adverse effects attributable to the intervention. Two authors independently scrutinized titles and abstracts identified from the search results. Two authors independently carried out risk of bias assessments, which took into account secure methods of randomization, allocation concealment, observer blinding, patient blinding, incomplete outcome data, selective outcome reporting and other bias. Two authors independently extracted data using a specially constructed data extraction
form. They undertook separate subgroup analyses of participants with more and less severe disability. For this update to the original review, the search identified 65 potentially relevant articles; and 12 studies met the inclusion criteria (872 participants) -- 4 trials studied the efficacy of electrical stimulation (313 participants), 3 trials studied exercises (199 participants), and 5 studies compared or combined some form of physical therapy with acupuncture (360 participants). For most outcomes these researchers were unable to perform meta-analysis because the interventions and outcomes were not comparable. For the primary outcome of incomplete recovery after 6 months, electro-stimulation produced no benefit over placebo (moderate quality evidence from 1 study with 86 participants). Low-quality comparisons of electro-stimulation with prednisolone (an active treatment) (149 participants), or the addition of electro-stimulation to hot packs, massage and facial exercises (22 participants), reported no significant differences. Similarly a meta-analysis from 2 studies, one of 3 months and the other of 6 months duration, (142 participants) found no statistically significant difference in synkinesis, a complication of Bell's palsy, between participants receiving electro- stimulation and controls. A single low- quality study (56 participants), which reported at 3 months, found worse functional recovery with electro-stimulation (mean difference (MD) 12.00 points (scale of 0 to 100) 95 % CI: 1.26 to 22.74). Two trials of facial exercises, both at high-risk of bias, found no difference in incomplete recovery at 6 months when exercises were compared to waiting list controls or conventional therapy. There is evidence from a single small study (34 participants) of moderate-quality that exercises are beneficial on measures of facial disability to people with chronic facial palsy when compared with controls (MD 20.40 points (scale of 0 to 100), 95 % CI 8.76 to 32.04) and from another single low-quality study with 145 people with acute cases treated for 3 months where significantly fewer participants developed facial motor synkinesis after exercise (risk ratio 0.24, 95 % CI 0.08 to 0.69). The same study showed statistically significant reduction in time for complete recovery, mainly in more severe cases (47 participants, MD -2.10 weeks, 95 % CI: -3.15 to -1.05) but this was not a pre-specified outcome in this meta-analysis. Acupuncture studies did not provide useful data as all were short and at high-risk of bias. None of the studies included adverse events as an outcome. The authors concluded that there is no high-quality evidence to support significant benefit or harm from any physical therapy for idiopathic facial paralysis. There is low-quality evidence that tailored facial exercises can help to improve facial function, mainly for people with moderate paralysis and chronic cases. There is low-quality evidence that facial exercise reduces sequelae in acute cases. The suggested effects of tailored facial exercises need to be confirmed with good quality RCTs.

On behalf of the American Academy of Neurology (AAN), Gronseth and Paduga (2012) reviewed evidence published since the 2001 AAN practice parameter regarding the effectiveness, safety, and tolerability of steroids and anti-viral agents for Bell palsy. These investigators searched Medline and the Cochrane Database of controlled clinical trials for studies published since January 2000 that compared facial functional outcomes in patients with Bell palsy receiving steroids/anti-viral agents with patients not receiving these medications. These investigators graded each study (Class I to IV) using the AAN therapeutic classification of evidence scheme. They compared the proportion of patients recovering facial function in the treated group with the proportion of patients recovering facial function in the control group. A total of 9 studies published since June 2000 on patients with Bell palsy receiving steroids/anti-viral agents were identified. Two of these studies were rated Class I because of high methodological quality. The authors concluded that for patients with new-onset Bell palsy, steroids are highly likely to be effective and should be offered to increase the probability of recovery of facial nerve function (2 Class I studies, Level A) (risk difference 12.8 % to 15 %). For patients with new-onset Bell palsy, anti-viral agents in combination with steroids do not increase the probability of facial functional recovery by more than 7 %. Because of the possibility of a modest increase in recovery, patients might be offered anti-virals (in addition to steroids) (Level C). Patients offered anti-virals should be counseled that a benefit from anti-virals has not been established, and, if there is a benefit, it is likely that it is modest at best.

An UpToDate review on “Bell's palsy: Prognosis and treatment in adults” (Ronthal, 2013) does not mention the use of graft/grafting as a management tool. Furthermore, it states that “Electrical nerve stimulation has been used to try to promote motor recovery in patients with Bell's palsy. Case reports
and small case series have suggested the possibility of some benefit with such treatment. However, in the absence of controlled trials of electrical stimulation, and given the lack of data even that such stimulation is safe (i.e., not harmful to patients with Bell's palsy), we recommend against its use.

Hoffman (1992) noted that the challenge of reconstruction in the paralyzed face is to provide symmetry both at rest and in active expression. Although functional considerations must take precedence, the patient with unilateral facial palsy faces social stigmata that are exceptionally difficult. When injury to the facial nerve is established, early nerve grafting on the ipsilateral side is the best treatment. In acoustic neuroma and other intra-cranial operations, the only real opportunity for grafting or repair is at the time of the procedure. If the nature of the injury is uncertain, a period of 12 months is allowed to elapse before consideration of intervention, which should be started if there is no return of function at that point. Electromyography may be of assistance in assessing minimal early return; if any early return is noted, further waiting is indicated. If there is no return at 1 year, cranial nerve XII to VII cross-over will preserve facial muscle tone and permit a more measured decision-making approach. Patients with multiple cranial nerves involved may be candidates for a partial hypoglossal transfer using a nerve graft, to attempt to preserve swallowing. In selected cases, cross-facial nerve grafting to the preserved facial muscles will give excellent results and obviate the need for local or distant muscle transfers.

When treating established paralysis of long duration, cross-facial nerve grafting with micro-neurovascular muscle transfer is the best option for symmetrical movement of the face. Temporalis and masseter muscle transfers should be reserved for the patient with intercurrent medical disease or the patient who refuses additional operations or operative sites. Static slings and other related procedures should be considered adjunctive but not primary treatment in the vast majority of cases. Although there are limitations in each of the procedures described, close co-operation between the otolaryngologist, the neurosurgeon, and the plastic surgeon can provide many patients with satisfactory rehabilitation from facial paralysis.

Gomez et al (1998) stated that several surgical procedures have been proposed through the years for the treatment of facial paralysis. Two basic dynamic options are available:

I. Reconstruction of nerve continuity through direct micro-suture, with interposition grafts or nerve transpositions, and
II. Regional muscular transposition, most often using the temporalis.

Facial re-animation with the temporalis transfer has withstood the test of time and still is a reference technique. In a few weeks, good results can be obtained with a single and rather simple surgical procedure. Functional free flaps have been used with increasing frequency in the last 2 decades, most often combining a cross-facial nerve graft followed by a gracilis free flap 9 months later. With this method there is a potential for restoration of spontaneous facial mimetic function.

Chuang (2008) noted that long-standing facial paralysis requires the introduction of viable, innervated dynamic muscle to restore facial movement. The options include regional muscle transfer and microvascular free tissue transfer. The choice is made by physician and patient together, taking into account their preferences and biases. Muscle-alone free tissue transfer is the author’s preferred option for re-animation of uncomplicated facial paralysis without skin or soft tissue deficits. Combined muscle and other tissue (most are skin flap) is another preferred option for more challenging complex facial paralysis with skin or soft tissue deficits after tumor excision. Gracilis flap is the author's first choice of muscle transplantation for both reconstructions. From 1986 to 2006, gracilis functioning free muscle transplantation (FFMT) was performed at Chang Gung Memorial Hospital for facial re-animation in 249 cases of facial paralysis. The main etiology is post-operative complication and Bell's palsy. The innervating nerve comes mostly from contralateral facial nerve branches, few from ipsilateral facial nerve due to tumor ablation, and from ipsilateral motor branch to masseter or spinal accessory nerve due to Mobius syndrome. The author has used a short nerve graft (10 to 15 cm) to cross the face in the first stage; after a 6- to 9-month waiting period, gracilis FFMT was performed for the 2nd-stage of the reconstruction. The technique of evolution has shown encouraging results to achieve the goal of rapid restoration and fewer scars on the donor leg.
Frey and colleagues (2010) stated that the currently most effective reconstructive techniques for reanimation of the unilaterally or bilaterally paralyzed face includes all important techniques of neuromuscular reconstruction as well as of supplementary static procedures, which contribute significantly to the efficiency and quality of the functional overall result. Attention is paid to the best indications at the best time since onset of the facial palsy, depending on the age of the patient, the cause of the lesion, and the compliance of the patient for a long-lasting and complex rehabilitation program. Immediate neuromuscular reconstruction of mimic function is favorable by nerve suture or nerve grafting of the facial nerve, or by using the contralateral healthy facial nerve via cross-face nerve grafting as long as the time since onset of the irreversible palsy is short enough that the paralyzed mimic muscles can still be re-innervated. For the most frequent indication, the unilateral irreversible and complete palsy, a 3-stage concept is described including cross-face nerve grafting, free functional gracilis muscle transplantation, and several supplementary procedures. In patients with limited life expectancy, transposition of the masseteric muscles is favored. Bilateral facial palsy is treated by bilateral free gracilis muscle transplantation with the masseteric nerve branches for motor re-innervation. Functional upgrading in incomplete lesions is achieved by cross-face nerve grafting with distal end-to-side neurorrhaphy or by functional muscle transplantation with ipsilateral facial nerve supply.

Momeni et al (2010) noted that one of the most demanding areas in plastic surgery is reconstruction of the smile in the setting of facial palsy. A multitude of surgical techniques and approaches have been proposed with variable success rates. The most frequently applied treatment algorithm is a 2-stage approach with placement of a cross-facial nerve graft (CFNG) initially and subsequent free functional muscle transfer. As this approach has several limitations, the authors have performed single-stage reconstructions utilizing the motor nerve to the masseter as the donor nerve. A total of 4 patients underwent this single-stage reconstruction for facial palsy between July 2007 and May 2008. In all patients free functional transfer of the gracilis muscle was performed using the motor nerve to the masseter as the donor nerve. Outcome measures were functional result as well as patient satisfaction. The intra-operative as well as post-operative course was uneventful in all patients. In only 1 patient these researchers encountered a small area of delayed wound healing which was amenable to conservative treatment. In all patients voluntary contraction of the gracilis muscle was visible after a mean period of 2.5 months. All patients displayed a high level of satisfaction with the functional result. The authors concluded that utilizing the motor nerve to the masseter muscle as a donor nerve allows single-stage microsurgical reconstruction of the smile in the setting of facial palsy with reproducible results.

Bianchi et al (2010) stated that facial paralysis is a congenital or acquired disorder of varying severity leading to an asymmetric or absent facial expression. It represents an important debilitation from both esthetic and functional points of view. These investigators reported their experience with patients treated with gracilis muscle transplantation innervated by the motor nerve to the masseter muscle. They discussed the surgical technique and the functional and esthetic results and evaluated the effectiveness of this donor nerve in providing adequate innervation to the muscle transfer for lower facial reanimation. A total of 15 patients with unilateral facial paralysis were seen and surgically treated at the Department of Maxillofacial Surgery, University of Parma, Parma, Italy, between 2003 and 2007. In this study the authors reported on 8 cases treated with gracilis muscle transfer re-innervated by the motor nerve to the masseter muscle. In this series all free-muscle transplantsations survived transfer, and no flap was lost. Facial symmetry at rest and while smiling was excellent or good in all patients, and the authors observed a significant improvement in speech and oral competence. With practice, the majority of patients developed the ability to smile spontaneously and without jaw movement. The authors considered the masseter motor nerve a powerful and reliable donor nerve, allowing one to obtain a commissure and upper lip movement similar to those of the normal site for amount and direction. The authors think that there may be a larger role for the masseter motor nerve for innervation of patients with unilateral facial paralysis who would otherwise have been considered candidates for cross-facial nerve graft innervation of the muscle transfer.
Ferguson et al (2011) stated that the face can be re-animated after long-term paralysis by free micro-neurovascular tissue transfer. Flaps from gracilis and pectoralis minor usually require a 2-stage procedure with a cross-face nerve graft. Latissimus dorsi has a much longer muscular nerve, the thoraco-dorsal nerve, which could avoid the need for a 2nd cross-face nerve graft. These researchers hypothesized that the neurovascular pedicles of small segments of latissimus dorsi would be long enough to reach the opposite side of the face and to provide a reliable blood and nerve supply to the flaps. To test this hypothesis, the thoraco-dorsal pedicle and its primary branches were dissected in 11 embalmed cadavers. The segmental vessels and nerves were then traced in a series of simulated flaps approximately 8 to 10 cm × 2 to 3 cm by micro-dissection, tissue clearing and histology. The thoraco-dorsal pedicle is 10 to 14 cm long to where it enters the muscle, and with intra-muscular dissection small chimeric muscle segments 8 to 10 cm × 2 to 3 cm can be raised with a clearly defined neurovascular supply. Using micro-dissection the neurovascular pedicle can be lengthened to reach across the face. Segmental arteries and nerves extended to the distal end of all the flaps examined. Artery, vein and nerve run together and are of substantial diameter. The authors concluded that small muscle segments of latissimus dorsi can be raised on long neurovascular pedicles. The vessels and nerves are substantial and the likelihood of surgical complications such as flap necrosis and functional disuse on transplantation appear low. Although in the authors' opinion the use of cross-face nerve grafts and transfer of smaller muscle flaps remains the gold standard in facial re-animation in straightforward cases, the micro-dissected latissimus dorsi flap is a useful option in complex cases of facial reanimation. Facial re-animation using micro-dissected segments of latissimus dorsi has been performed in 4 complex cases of facial paralysis.

In a retrospective study, Gousheh et al (2011) reported the findings of 655 cases of unilateral facial paralysis that were treated by different surgical methods to achieve dynamic reanimation of facial muscle movement. The recovery of both truly spontaneous smile and facial muscle movement was evaluated independently. The authors performed 505 two-stage gracilis, 1 rectus abdominis, and 14 single-stage latissimus dorsi micro-neurovascular muscle transfers, in addition to 28 cross-facial facial nerve neurotization procedures. These procedures were based on neurotization of the paralyzed region by the contralateral healthy facial nerve. Procedures involving motor nerves or muscle beyond the territory of the facial nerve included 73 temporalis muscle transpositions, 4 lengthening temporalis myoplasty procedures, 26 neurotizations by the hypoglossal nerve, and 4 neurotizations by the spinal accessory nerve. Patients treated by techniques based on the motor function of nerves other than the facial nerve did not recover spontaneous smile. Neurotization by the facial nerve, however, did result in the recovery of spontaneous smile in all satisfactory or better outcomes. Recovery of lip commissure movement based on neurotization by the contralateral healthy facial nerve was better than that of the remaining groups (p < 0.0001). The authors concluded that temporalis muscle transposition and lengthening myoplasty are acceptable options for patients who are not good candidates for neurotization by the facial nerve. For the restoration of both truly spontaneous smile and facial muscle movement, free micro-neurovascular muscle transfer neurotized by the contralateral healthy facial nerve has become the authors' first-choice surgical technique.

An UpToDate review on “Facial nerve palsy in children” (Clark, 2014) states that “Surgical techniques for congenital or permanently acquired lesions include muscle transfers and nerve grafts …. Surgical reanimation techniques may be considered in children with congenital or permanently acquired facial nerve palsy. These techniques do not completely restore normal physiologic function, although they may aid the child psychologically. Surgical procedures are divided into static procedures that provide symmetry of the mouth at rest and reanimation techniques that allow facial expression. They may involve regional muscle transfers, nerve crossovers, cable grafts, and free muscle grafts”.

Li et al (2015) conducted a systematic review and meta-analysis to assess the effectiveness of acupuncture for Bell’s palsy. These investigators searched PubMed, Embase, and the Cochrane Central Register of Controlled Trials, irrespective of any language restrictions. Randomized controlled trials comparing acupuncture with other therapies for Bell’s palsy in adults or children were included. A total of 14 involving 1,541 individuals were included in this meta-analysis. Significant association was observed in acupuncture with a higher effective response rate for Bell’s palsy (RR, 1.14; 95 % CI: 1.04
to 1.25; p = 0.005), but there was a heterogeneity among the studies (I² = 87 %). An assessment of the included studies revealed a high risk of bias in methodological quality. An evaluation of the incidence of complications was not available, owing to incomplete data. The authors concluded that acupuncture appeared to be an effective therapy for Bell's palsy, but there was insufficient evidence to support the safety and effectiveness of acupuncture. Moreover, they stated that the results should be interpreted cautiously, because of the poor quality and heterogeneity of the included studies.

Wang et al (2015) evaluated the effectiveness of acupuncture combined with vitamin B-12 acupoint injection versus acupuncture alone to reduce incomplete recovery in patients with Bell's palsy. A computer-based online retrieval of Medline, Web of Science, CNKI, CBM databases until April 2014 was performed for relevant trials, using the key words "Bell's palsy or idiopathic facial palsy or facial palsy" and "acupuncture or vitamin B-12 or methylcobalamin". All RCTs that compared acupuncture with acupuncture combined with vitamin B-12 in patients with Bell's palsy were included in the meta-analysis. The initial treatment lasted for at least 4 weeks. The outcomes of incomplete facial recovery were monitored. The scoring index varied and the definition of healing was consistent. The combined effect size was calculated by using RR with 95 % CI using the fixed effect model of Review Manager. Incomplete recovery rates were chosen as the primary outcome. A total of 5 studies involving 344 patients were included in the final analysis. Results showed that the incomplete recovery rate of Bell's palsy patients was 44.50 % in the acupuncture combined with vitamin B-12 group, but 62.57 % in the acupuncture alone group. The major acupoints were Taiyang (EX-HN5), Jiache (ST6), Dicang (ST4) and Sibai (ST2). The combined effect size showed that acupuncture combined with vitamin B-12 was better than acupuncture alone for the treatment of Bell's palsy (RR = 0.71, 95 % CI: 0.58 to 0.87; p = 0.001), this result held true when 8 patients lost to follow-up in 1 study were included into the analyses (RR = 0.70, 95 % CI: 0.58 to 0.86; p = 0.0005). In the subgroup analyses, the therapeutic effect in patients of the electro-acupuncture subgroup was better than in the non-electro-acupuncture subgroup (p = 0.024). There was no significant difference in the incomplete recovery rate by subgroup analysis on drug types and treatment period. Most of the included studies were moderate or low quality, and bias existed. The authors concluded that in patients with Bell's palsy, acupuncture combined with vitamin B-12 can reduce the risk of incomplete recovery compared with acupuncture alone in this meta-analysis. Moreover, they stated that because of study bias and methodological limitations, this conclusion is uncertain and the clinical application of acupuncture combined with vitamin B-12 requires further exploration.

Gagyor et al (2015) stated that corticosteroids are widely used in the treatment of idiopathic facial paralysis (Bell's palsy), but the effectiveness of additional treatment with an anti-viral agent is uncertain. Significant morbidity can be associated with severe cases of Bell's palsy. In a Cochrane review, these investigators evaluated the effects of anti-viral treatments alone or in combination with any other therapy for Bell's palsy. On October 7, 2014 the authors searched the Cochrane Neuromuscular Disease Group Specialized Register, CENTRAL, MEDLINE, EMBASE, LILACS, DARE, NHS EED, and HTA. They also reviewed the bibliographies of the identified trials and contacted trial authors and known experts in the field and relevant drug companies to identify additional published or unpublished data. They searched clinical trials registries for ongoing studies. These researchers considered RCTs or quasi-RCTs of antivirals with and without corticosteroids versus control therapies for the treatment of Bell's palsy. They excluded trials that had a high risk of bias in several domains. Pairs of authors independently assessed trials for relevance, eligibility, and risk of bias, using standard Cochrane procedures. A total of 11 trials, including 2,883 participants, met the inclusion criteria and were included in the final analysis. The authors added 4 studies to the previous review for this update. Some of the trials were small, and a number were at high or unclear risk of bias. Other trials did not meet current best standards in allocation concealment and blinding. They found no significant benefit from adding anti-virals to corticosteroids in comparison with corticosteroids alone for people with Bell's palsy (RR 0.69, 95 % CI: 0.47 to 1.02, n = 1,715). For people with severe Bell's palsy (House-Brackmann scores of 5 and 6 or the equivalent in other scales), these researchers found a reduction in the rate of incomplete recovery at month 6 when anti-virals plus corticosteroids were used (RR 0.64, 95 % CI: 0.41 to 0.99, n = 478). The outcome for the participants receiving corticosteroids alone was
significantly better than for those receiving anti-virals alone (RR 2.09, 95 % CI: 1.36 to 3.20, n = 1,169). The treatment effect of placebo was significantly lower than that of anti-virals plus corticosteroids (RR 0.56, 95 % CI: 0.41 to 0.76, n = 658). Anti-virals alone had a non-significant detrimental effect on the outcome compared with placebo (RR 1.10, 95 % CI: 0.87 to 1.40, n = 658). In 3 trials comparing anti-virals and corticosteroids with corticosteroids and placebo that assessed this outcome, the authors found a significant difference in long-term sequelae in favor or anti-virals plus corticosteroids (RR 0.73, 95 % CI: 0.54 to 0.99, n = 869). Three trials comparing anti-virals alone with corticosteroids alone investigating this outcome showed fewer sequelae with corticosteroids (RR 1.44, 95 % CI: 1.11 to 1.85, n = 873). They found no data on long-term sequelae for other comparisons. Adverse event data were available in 3 studies giving comparison data on 1,528 participants. None of the 4 comparisons (anti-virals plus corticosteroids versus corticosteroids plus placebo or no treatment; anti-virals versus corticosteroids; anti-virals plus corticosteroids versus placebo; anti-virals versus placebo) showed significant differences in adverse events between treatment and control arms. They could find no correlation with specific treatment within these results. The authors concluded that moderate-quality evidence from RCTs showed no additional benefit from the combination of anti-virals with corticosteroids compared to corticosteroids alone or with placebo, and no benefit from anti-virals alone compared to placebo, for the treatment of Bell's palsy. Moderate-quality evidence showed a small but just significant benefit of combination therapy compared with corticosteroids alone in severe Bell's palsy. They found no significant increase in adverse events from the use of anti-virals compared with either placebo or corticosteroids.

**Neuromuscular Ultrasound for the Diagnosis of Bell's Palsy:**

In a pilot study, Tawfik et al (2015) evaluated the role of neuromuscular ultrasound in Bell's palsy. A second objective was to assess the possibility of any associated vagus nerve abnormality. A total of 12 healthy controls and 12 Bell's palsy patients were recruited. The bilateral facial nerves, vagus nerves, and frontalis muscles were scanned using an 18-MHz linear array transducer. Facial nerve diameter, vagus nerve cross-sectional area, and frontalis thickness were measured. Mean facial nerve diameter was 0.8 ± 0.2 mm in controls and 1.1 ± 0.3 mm in patients group. The facial nerve diameter was significantly larger in patients than controls (p = 0.006, 95 % CI for the difference between groups of 1.12 to 0.48), with a significant side-to-side difference in patients as well (p = 0.004, 95 % CI: for side-to-side difference of 0.08 to 0.52). Receiver operating characteristic (ROC) curve analysis of the absolute facial nerve diameter revealed a sensitivity of 75% and a specificity of 70%. No significant differences in vagus nerve cross-sectional area or frontalis thickness were detected between patients and controls. The authors concluded that ultrasound can detect facial nerve enlargement in Bell's palsy and may have a role in assessment, or follow-up, of Bell's palsy and other facial nerve disorders. Moreover, they stated that the low sensitivity of the current technique precludes its routine use for diagnosis; however, this study demonstrated its validity and potential for future research.

**Intra-Tympanic Steroid Injection for the Treatment of Bell's Palsy:**

In a prospective, investigator blinded, randomized study, Chung et al (2014) examined the safety and effectiveness of intra-tympanic steroid injection for the treatment of Bell's palsy. Patients who received treatment for Bell's palsy from December 2007 to March 2011 were randomly divided into 2 groups: (i) the control group (n = 17) was treated with systemic steroid plus anti-viral agent, and (ii) the treatment group received intra-tympanic steroid injection combined with medications (IT group, n = 14). Facial functions were evaluated on a regular basis up to 6 months. Facial nerve functions of initial presentation and follow-up were evaluated with House-Brackmann (H-B) system. Primary outcome was complete recovery rate of 6 months. Secondary outcomes included improvement of H-B grade within 3 weeks, time of first improvement in facial function, and cumulative recovery rate. In addition, subgroup analysis of H-B grade over than IV was performed. Complete recovery rate was not different between groups. Time of first improvement was shorter in IT group (p = 0.043); and IT group had a better cumulative recovery rate (p = 0.041) and showed the significant improvement in H-B grade within 3 weeks compared with control group (p = 0.045). In severe facial palsy, complete recovery rate
of IT group and control group were 80 % and 50 % (p = 0.16), and IT groups showed the significant facial improvement within 3 weeks (p = 0.025). There were no major adverse effects of intra-tympanic injection. The authors concluded that intra-tympanic steroid injection might be a safe and useful adjuvant treatment modality for Bell's palsy. These preliminary findings need to be validated by well-designed studies.

**Nerve Growth Factor for the Treatment of Bell's Palsy:**

In a meta-analysis, Su et al (2015) assessed the safety and effectiveness of nerve growth factor (NGF) in the treatment of Bell's palsy. PubMed, the Cochrane Central Register of Controlled Trials, Embase and a number of Chinese databases, including the China National Knowledge Infrastructure, China Biology Medicine disc, VIP Database for Chinese Technical Periodicals and Wan Fang Data, were used to collect RCTs of NGF for Bell's palsy. The span of the search covered data from the date of database establishment until December 2013. The included trials were screened comprehensively and rigorously. The efficacies of NGF were pooled via meta-analysis performed using Review Manager 5.2 software. Odds ratios and 95 % CIs were calculated using the fixed-effects model. The authors concluded that the meta-analysis of 8 RCTs showed favorable effects of NGF on the disease response rate (n = 642; OR, 3.87; 95 % CI: 2.13 to 7.03; p < 0.01; I² = 0%). However, they stated that the evidence supporting the effectiveness of NGF for the treatment of Bell's palsy is limited. They noted that the number and quality of trials are too low to form solid conclusions. The authors stated that further meticulous RCTs are needed to overcome the limitations identified in the present study.

**Measurement of Blood Levels of Total and Native Thiol and Disulphide Activity as a Pathogenetic Marker of Bell's Palsy:**

In a prospective study, Babademez and colleagues (2017) examined the relationship between Bell's palsy and a novel oxidative stress parameter, thiol/disulphide homeostasis. A total of 77 patients with Bell's palsy and 38 healthy controls were included in this study. The blood levels of total and native thiol and disulphide activity were measured, and their levels were compared in the patients and controls. There were statistically significant differences between the patients and controls regarding thiol/disulphide parameters. The mean native thiol and total thiol were significantly lower and disulphide levels were higher in the Bell's palsy than controls. On binary logistic regression analysis, the created model showed 45.3 % variation. The cut-off value was 18.95 for disulphides. The authors concluded that total and native thiol levels were low in the Bell's palsy; this metabolic disturbance may have a role in the pathogenesis of Bell's palsy. These preliminary findings need to be validated by well-designed studies.

**Neural Therapy:**

Yavuz and colleagues (2016) described the case of a 42-year old man with a type of facial nerve palsy of the lower motor neurons (LMNs) on the right side, who was treated with neural therapy, which is an injection treatment designed to repair the dysfunction of the autonomic nervous system by correcting the electrical condition of cells and nerves. Thus, the bioelectric disturbance at a specific site or nerve ganglion can be restored to normality. In neural therapy, local anesthetics (e.g., lidocaine, or procaine) are used. Neural therapy entails the injection of local anesthetics into acupuncture points, autonomic ganglia, endocrine glands, peripheral nerves, scar tissues, trigger points, and other tissues. Some clinical trials and case reports had shown that neural therapy could be an effective treatment for relieving pain and improving functional loss or disability for patients with various disorders. The authors believed that this case review was the first description of the effectiveness of neural therapy for patients with Bell's palsy; however, the effectiveness of neural therapy is still in question.
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:

15758  Free fascial flap with microvascular anastomosis
15840 - 15845  Graft for facial nerve paralysis
20920 - 20922  Fascia lata graft
64716  Neuroplasty and/or transposition; cranial nerve (specify)
64742  Transection or avulsion of; facial nerve, differential or complete
64864 - 64865  Suture of facial nerve
64866 - 64868  Anastomosis; facial-spinal, facial-hypoglossal or facial-phrenic
64885 - 64886  Nerve graft (includes obtaining graft), head or neck
69740 - 69745  Suture facial nerve, intratemporal, with or without graft or decompression
67912  Correction of lagophthalmos, with implantation of upper eyelid load (e.g., gold weight)
95933  Orbicularis oculi (blink) reflex, by electrodiagnostic testing

CPT codes not covered for indications listed in the CPB:

Blood level measurement of total and native thiol and disulphide activity, neural therapy- no specific code:

15574  Formation of direct or tubed pedicle, with or without transfer; forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands or feet
15576  Formation of direct or tubed pedicle, with or without transfer; eyelids, nose, ears, lips, or intraoral
15620  Delay of flap or sectioning of flap (division and inset); at forehead, cheeks, chin, neck, axillae, genitalia, hands, or feet
15630  Delay of flap or sectioning of flap (division and inset); at eyelids, nose, ears, or lips
15731  Forehead flap with preservation of vascular pedicle (eg, axial pattern flap, paramedian forehead flap)
15732  Muscle, myocutaneous, or fasciocutaneous flap; head and neck (eg, temporalis, masseter muscle, sternocleidomastoid, levator scapulae)
15740 - 15757, 15760 - 15777  other flaps and grafts
61590  Infratemporal pre-auricular approach to middle cranial fossa (parapharyngeal space, infratemporal and midline skull base, nasopharynx), with or without disarticulation of the mandible, including parotidectomy, craniotomy, decompression and/or mobilization of the facial nerve and/or petrous carotid artery
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>61595</td>
<td>Transtemporal approach to posterior cranial fossa, jugular foramen or midline skull base, including mastoidectomy, decompression of sigmoid sinus and/or facial nerve, with or without mobilization</td>
</tr>
<tr>
<td>61596</td>
<td>Transcochlear approach to posterior cranial fossa, jugular foramen or midline skull base, including labyrinthectomy, decompression, with or without mobilization of facial nerve and/or petrous carotid artery</td>
</tr>
<tr>
<td>64612 - 64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves</td>
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<tr>
<td>64732 - 64740</td>
<td>Transection or avulsion of; supraorbital, infraorbital, mental, inferior alveolar or lingual nerve</td>
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<tr>
<td>64905</td>
<td>Nerve pedicle transfer; first stage</td>
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<tr>
<td>64907</td>
<td>second stage</td>
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<tr>
<td>64911</td>
<td>with autogenous vein graft (includes harvest of vein graft), each nerve</td>
</tr>
<tr>
<td>64912</td>
<td>Nerve repair; with nerve allograft, each nerve, first strand (cable)</td>
</tr>
<tr>
<td>69720</td>
<td>Decompression facial nerve, intratemporal; lateral to geniculate ganglion</td>
</tr>
<tr>
<td>69725</td>
<td>including medial to geniculate ganglion</td>
</tr>
<tr>
<td>69801</td>
<td>Labyrinthotomy, with perfusion of vestibuloactive drug(s); transcanal</td>
</tr>
<tr>
<td>69955</td>
<td>Total facial nerve decompression and/or repair (may include graft)</td>
</tr>
<tr>
<td>76536</td>
<td>Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation [neuromuscular ultrasound]</td>
</tr>
<tr>
<td>90867</td>
<td>Therapeutic repetitive transcranial magnetic stimulation treatment; planning</td>
</tr>
<tr>
<td>90868</td>
<td>delivery and management, per session</td>
</tr>
<tr>
<td>90869</td>
<td>subsequent motor threshold re-determination with delivery and management</td>
</tr>
<tr>
<td>+ 95873</td>
<td>Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>+ 95874</td>
<td>Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>97014</td>
<td>Application of a modality to one or more areas; electrical stimulation (unattended)</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes</td>
</tr>
<tr>
<td>97810</td>
<td>Acupuncture, one or more needles, without electrical stimulation; initial 15 minutes of personal one-on-one contact with patient</td>
</tr>
<tr>
<td>+ 97811</td>
<td>without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in</td>
</tr>
</tbody>
</table>
addition to code for primary procedure)

97813 with electrical stimulation; initial 15 minutes of personal one-on-one contact with patient

97814 with electrical stimulation; each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

99183 Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

HCPCS codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4575</td>
<td>Topical hyperbaric oxygen chamber, disposable</td>
</tr>
<tr>
<td>A4595</td>
<td>Electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES)</td>
</tr>
<tr>
<td>A4639</td>
<td>Replacement pad for infrared heating pad system, each</td>
</tr>
<tr>
<td>E0221</td>
<td>Infrared heating pad system</td>
</tr>
<tr>
<td>E0446</td>
<td>Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories</td>
</tr>
<tr>
<td>E0720</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation</td>
</tr>
<tr>
<td>E0730</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation</td>
</tr>
<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
<tr>
<td>G0277</td>
<td>Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval</td>
</tr>
<tr>
<td>J0585</td>
<td>Botulinum toxin type A, per unit</td>
</tr>
<tr>
<td>J0587</td>
<td>Botulinum toxin type B, per 100 units</td>
</tr>
<tr>
<td>J3420</td>
<td>Injection, vitamin B-12 cyanocobalamin, up to 1,000 mcg</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G51.0</td>
<td>Bell's palsy [facial palsy]</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

51. Ronthal M. Bell's palsy: Prognosis and treatment in adults. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed July 2013.


60. Clark GD. Facial nerve palsy in children. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2014.


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0745 Bell's Palsy

There are no amendments for Medicaid.