Clinical Policy Bulletin:
Motor Cortex Stimulation

Number: 0755

Policy

Aetna considers motor cortex stimulation experimental and investigational for the treatment of the following indications (not an all-inclusive list) because its effectiveness has not been established:

- Amyotrophic lateral sclerosis
- Chronic refractory pain (e.g., central pain syndromes, peripheral neuropathic pain, phantom limb pain, and trigeminal neuropathic pain)
- Dysphagia
- Dystonia secondary to a focal basal ganglia lesion
- Movement disorders
- Parkinson's disease
- Post-stroke hemiparesis

Background

Motor cortex stimulation (MCS) has been used to treat various chronic refractory pain conditions such as trigeminal neuralgia, post-stroke pain (PSP), and other nerve/brain injury pain syndromes. It entails implantation of electrodes over the primary motor cortex. One or more electrodes are placed extra-durally over the motor cortex via a burr hole or a small craniotomy, and these electrodes are then connected to an implantable, battery-powered, neurostimulator. This procedure is usually performed in two separate operations: (i) computer-aided neuro-navigation techniques and magnetic resonance imaging (MRI) images are used to guide implantation of electrode(s); and (ii) a second operation is performed for implantation of a neurostimulator if stimulation of the motor cortex is successful in alleviating the patient's pain. The neurostimulator placed subcutaneously near the clavicle, and is connected to the electrode(s). An external radio transmitter is used to adjust the electrical impulses depending on the level of pain. Maarrawi et al (2007) noted that MCS is associated with focal cerebral blood flow changes involving regions with high density of opioid receptors. These researchers
suggested that MCS-related pain relief is probably due to MCS-induced release of endogenous opioids in brain structures involved in the processing of pain.

While MCS has been employed in the treatment of a variety of chronic refractory pain conditions, there is only limited evidence regarding its effectiveness. Available evidence is largely derived from small, uncontrolled, case studies.

Ebel et al (1996) reported the results of MCS in treating severe trigeminal neuropathic pain (TNP) (n = 7). In all but one case the impulse-generator was implanted after a successful period of test stimulation. "Successful" means a pain reduction of more than 50% as assessed with a visual analog scale (VAS). Excluding one case, in which a prolonged focal seizure resulting in a post-ictal speech arrest occurred during test stimulation, there have been no operative complications and the post-operative course was uneventful. In all the other patients the pain inhibition appeared below the threshold for producing motor effects. Initially these patients reported a good-to-excellent pain relief. In 3 of 6 patients a good-to-excellent pain control was maintained for a follow-up period of 5 months to 2 years. In the remaining 3 patients the positive effect decreased over several months.

Nguyen et al (2000) studied the use of MCS in the treatment of central pain (n = 32). The mean follow-up was 27.3 months. Ten of the 13 patients (77%) with central pain and 10 of the 12 patients (83.3%) with neuropathic facial pain experienced substantial pain relief. One of the 3 patients with post-paraplegia pain was clearly improved. A satisfactory result was obtained in 1 patient with pain related to plexus avulsion and in 1 patient with pain related to intercostal herpes zoster. None of the patients developed epileptic seizures. The authors concluded that chronic MCS is an effective method in treating certain forms of refractory pain.

Mogilner and Rezai (2001) noted that chronic epidural MCS has been shown to have promise in the treatment of patients with refractory deafferentation pain. A total of 5 patients underwent MCS in which functional imaging guidance was used. Prior to surgery, patients underwent MRI with skin fiducial markers placed on standard anatomical reference prints, followed by magneto-encephalography mapping of the sensory and motor cortices. In 2 patients, functional MRI was also performed using a motor task paradigm. The functional imaging data were integrated into a frameless stereotactic database by using a 3-dimensional co-registration algorithm. Subsequently, a frameless stereotactic craniotomy was performed using the integrated anatomical and functional imaging data for surgical planning. Intra-operative somato-sensory evoked potentials (SSEPs) and direct stimulation were used to confirm the target and final placement of the electrode. Direct stimulation and SSEPs performed intra-operatively confirmed the accuracy of the functional imaging data. Trial periods of stimulation successfully reduced pain in 3 of the 5 patients who then underwent permanent internal placement of the system. At a mean 6-month follow-up, these patients reported an average reduction in pain of 55% on a VAS.

Devulder and colleagues (2002) noted that amitriptyline and sodium channel blockers are the drugs of first-choice for the treatment of central pain. If oral or transdermal drug delivery is not indicated or ineffective, the intra-thecal administration route can be attempted with baclofen, clonidine, opioids and
midazolam. Invasive electro-stimulation is the last treatment option. Thalamic stimulation can be tried in spinal cord injuries, and MCS is sometimes the last resort. Rainov and Heidecke (2003) reported long-term follow-up of 2 patients with unilateral facial neuropathic pain due to idiopathic trigeminal neuropathy and surgical trauma to the glosso-pharyngeal nerve, respectively. These patients failed other modalities for pain relief. Electrical stimulation of the motor cortex with a quadripolar electrode contralateral to the painful area of the face was tried and resulted in immediate analgesia with more than 50 % pain reduction. During a follow-up period of 72 months, a sufficient (greater than 50 %) and stable analgesic effect of MCS was observed.

Henderson et al (2004) stated that MCS may serve as an adjunct in managing neuropathic pain after other conservative and interventional methods have failed. However, the magnitude and duration of the benefit are highly variable, with a significant percentage of patients losing pain relief over time. These researchers examined if intensive re-programming could re-capture the beneficial effects of MCS (n = 6). Patients’ average age was 50 years (range of 26 to 71). The diagnoses were TNP (n = 2), complex regional pain syndrome (CRPS) I (n = 2), phantom limb pain (n = 1) and PSP (n = 1). The mean duration of pain was 6 years. The MCS benefit had initially lasted for a mean of 7.16 months (range of 2 to 18 months). After re-programming, 5 of 6 patients experienced improvement in pain. Average VAS scores decreased from 7.44 to 2.28 (p < 0.001) in those patients who responded to re-programming. Three patients experienced seizures during re-programming. No patient experienced seizures at their therapeutic settings. Pain control was maintained after discharge. These researchers found that intensive re-programming can re-capture the benefit of MCS in patients who have lost pain control.

Tirakotai et al (2004) noted that MCS is an alternative treatment for central pain syndromes. A total of 5 patients suffering from central pain underwent MCS with the guidance of a frameless stereotactic system. The neuro-navigation was used for identification of the pre-central gyrus and accurate planning of the single burr hole. The exact location was re-confirmed by an intra-operative stimulation test. Post-operative clinical and neuro-radiological evaluations were performed in each patient. The navigation system worked properly in all 5 cases. Determination of the placement of stimulating electrode was possible in every case. All patients obtained post-operative pain relief. No surgical complication occurred, and the post-operative course was uneventful in all patients.

In a prospective study (n = 10), Brown and Pilitsis (2005) used the McGill Pain Questionnaire, VAS, and an inventory of drug consumption to review the results of treating patients with TNP by means of MCS. Implantation of electrodes was performed via intra-operative neuro-navigation and cortical mapping for stimulation site targeting. Nine patients had TNP from post-herpetic neuralgia, surgical injury, or unknown cause, and 1 patient had pain of central origin. Patients were evaluated with multi-modality scales before, immediately after, and at designated intervals after surgery. Eight patients underwent permanent implantation after a trial evaluation. In 2 patients, the stimulating electrodes were removed after an unsuccessful trial: 1 had a lateral medullary infarct leading to central pain, and in the other patient, there was no explanation for the pain. The average duration of pain before surgery was 6 years. Post-operatively, there was an 88 % rate of
immediate pain relief (greater than 50 % on VAS score) and a 75 % rate of pain
relief at mean follow-up of 10 months (range of 3 to 24 months). Mean pre-
operative McGill Pain Questionnaire total pain rating index was 57 (higher than
that observed in causalgia) for patients who did not undergo implantation and 53
for those who underwent implantation. Mean McGill Pain Questionnaire pain
rating index at mean follow-up of 10 months was 24 (55 % decrease). Mean VAS
score pre-operatively was 9 in patients with stimulator implants and 8 in those
whose stimulator was removed after the trial. Immediate post-operative mean
VAS score was 1. This score stabilized 3 months after surgery. Patients with
implanted stimulators reduced their pain medication dose by a mean of more than
50 %. Three patients with facial weakness and sensory loss regained both
strength and discriminative sensation during stimulation. In another patient,
dysarthria improved. In a review of the literature, 29 (76 %) of 38 patients with
neuropathic facial pain treated with MCS achieved greater than 50 % pain relief.
The authors concluded that these results provided support for the use of MCS in
facial neuropathic pain and document pain improvement as measured by multi-
dimensional scales.

In a prospective study, Nuti et al (2005) evaluated the effects of MCS in the
treatment of refractory neuropathic pain (n = 31). The long-term outcome was
evaluated using 5 variables: (i) rate (%) of pain relief, (ii) pain scores as assessed
on VAS, (iii) post-operative decrease in VAS scores, (iv) reduction in analgesic
drugs intake, and (v) a dichotomic (yes/no) response to the question whether the
patient would accept, under similar circumstances, to be operated on again. Pain
relief was rated as excellent (greater than 70 % pain relief) in 10 % of cases, good
(40 to 69 %) in 42 %, poor (10 to 39 %) in 35 % and negligible (0 to 9 %) in 13 %.
Intake of analgesic drugs was decreased in 52 % of patients and unchanged in 45
%(unavailable data in 3 %), with complete withdrawal of analgesic drugs in 36 %
of patients. Twenty-one patients (70 %) declared themselves favorable to re-
intervention if the same beneficial outcome could be guaranteed. Neither pre-
operative motor status, pain characteristics, type or localization of lesions,
quantitative sensory testing, SSEPs, nor the interval between pain and surgery
were found to predict the effectiveness of MCS. The level of pain relief, as
evaluated in the first month following implantation was a strong predictor of long-
term relief (regression analysis, r = 0.744; p < 0.0001). These results indicated
that MCS can be a satisfactory and durable alternative to medical treatments in
patients with refractory pain, and suggested that the effectiveness of MCS may be
predicted in the first month of therapy.

Rasche et al (2006) analyzed retrospectively 17 patients with chronic neuropathic
pain who were treated with contralateral epidural stimulation electrodes; TNP was
diagnosed in 10 cases and PSP in 7 cases. The placement of the electrodes was
performed in local anesthesia using neuro-navigation and intra-operative neuro-
monitoring. A test trial of minimum 1 week including double-blind testing was
conducted and pain intensity was measured using a VAS. Correct placement of
the electrode was achieved in all patients using intra-operative neurophysiological
monitoring. Double-blind testing was able to identify 6 (35 %) non-responders. In
5 of 10 (50 %) with TNP and 3 of 7 (43 %) with PSP, a positive effect with pain
reduction greater than or equal to 50 % was observed. The mean follow-up
period was 3.6 years (range of 1 to 10 years) and included 1 patient with 10 years
of positive stimulation effect. The authors concluded that MCS is a treatment
option for patients with chronic neuropathic pain localized in the face or upper extremity.

In a review on neuro-stimulation for chronic non-cancer pain, Coffey and Lozano (2006) noted that neurostimulation to treat chronic pain includes approved and investigational therapies directed at the spinal cord, thalamus, peri-aqueductal or peri-ventricular gray matter, motor cortex, as well as peripheral nerves. Persistent pain following surgery and work-related or neural injuries are common indications for such treatments. In light of the risks, efforts, costs, and expectations associated with neuro-stimulating therapies, a careful re-examination of the methods used to gather evidence for this treatment’s long-term effectiveness is in order. The authors concluded that future analyses of emerging neuro-stimulating modalities for pain should require unambiguous diagnoses as an entry criterion and should involve the use of randomization, parallel control groups that receive sham stimulation, as well as blinding of patients, investigators, and device programmers. Given the chronicity of patient symptoms and stimulation therapies, effectiveness should be studied for 1 year or longer following implantation of the device. Meticulous methods are especially important to evaluate new therapies such as MCS. Henderson and Lad (2006) noted that MCS is a relatively new technique that has shown some promise in the treatment of TNP. This technique has the potential to revolutionize the treatment of chronic pain. The authors stated that it is important to evaluate MCS critically in a prospective, controlled fashion.

Cheshire (2007) noted that MCS, although having shown initial promise for TNP, seemed to be ineffective for classical TN. Lazorthes et al (2007) reported that the results of MCS on phantom limb pain are promising; and the conclusions of ongoing multi-center randomized clinical trials (RCTs) will be very useful and are likely to promote further research and clinical applications in this field. Cioni and Meglio (2007) stated that the indications for MCS included TNP and other types of central/peripheral deafferentation pain. The results reported in the literature were quite good; the mean long-term success rate was 80 % in facial pain and 53 % in non-facial pain. However, results from these researchers were less impressive; 4 of 14 (28 %) patients with chronic non-malignant pain experienced a greater than 40 % pain relief, but in 2 of them the effect faded with time. These investigators stated that it is time for a large, multi-center, prospective, randomized, double-blind study evaluating not only the effect of MCS on pain, but also the optimal electrode placement and stimulation parameters. Available guidelines indicate that RCTs are needed to ascertain the effectiveness of MCS in the treatment of chronic pain. The Reflex Sympathetic Dystrophy Syndrome Association’s treatment guidelines on CRPS (2006) listed MCS as an experimental procedure in the treatment algorithm of this condition. Furthermore, the guideline on assessment and management of chronic pain by the Institute for Clinical Systems Improvement (2007) stated that neurosurgical techniques for chronic pain resistant to an adequate conservative approach hold promise, but have limited scientific evidence. These invasive approaches include ablative techniques such as cingulotomy and mesencephalotomy, as well as stimulation techniques such as deep brain stimulation and MCS. In addition, the European Federation of Neurological Societies’ guidelines on neurostimulation therapy for neuropathic pain (Cruccu et al, 2007) stated that there is level C evidence (possibly effective, ineffective, or harmful) that MCS is useful in 50 to 60 % of
patients with central PSP as well as central or peripheral facial neuropathic pain, with small risk of medical complications. The evidence about any other condition remains insufficient. The authors stated that further controlled trials are needed for spinal cord stimulation in conditions other than failed back surgery syndrome and CRPS; and for MCS and deep brain stimulation in general. An assessment by the Institute for Clinical Effectiveness and Health Policy (Pichon-Riviere et al, 2007) concluded that MCS for central and neuropathic pain is an investigational technique.

More recently, MCS is also being studied for the treatment of other diseases. Several studies have specifically examined the use of MCS in treating Parkinson's disease (Cioni et al, 2007). Arle and Shils (2008) performed a literature search between 1991 and 2007 and found 512 cases using MCS. Although most of these addressed the treatment of pain (n = 422), 84 of them involved movement disorders. Moreover, Priori and Lefaucheur (2007) noted that the therapeutic effects of MCS in the treatment of movement disorders still need to be assessed in controlled studies. Arle and colleagues (2008) stated that although there have been some positive findings using MCS for Parkinson's disease, a larger study may be needed to better determine if it should be pursued as an alternative surgical treatment to deep brain stimulation.

Lima and Fregni (2008) conduct a systematic review and meta-analysis to quantify the efficacy of invasive and non-invasive MCS for the treatment of chronic pain. Medline and other databases were searched as data sources. Reference lists and conference abstracts were examined for further relevant articles. A total of 11 studies using non-invasive brain stimulation and 22 studies using invasive brain stimulation met the inclusion criteria. The results showed that weighted responder rate was 72.6 % (95 % confidence interval [CI]: 67.7 to 77.4) for the invasive stimulation studies and 45.3 % (95 % CI: 39.2 to 51.4) for the non-invasive stimulation studies. This difference was significant. For the non-invasive stimulation studies, the random effects model revealed that the number of responders in the active group was significantly higher as compared with sham stimulation group (risk ratio of 2.64) (95 % CI: 1.63 to 4.30). The authors concluded that this meta-analysis shows that two different techniques of brain stimulation of motor cortex -- invasive and non-invasive -- can exert a significant effect on pain in patients with chronic pain. They discussed potential reasons that invasive brain stimulation showed a larger effect in this meta-analysis; these findings encourage continuation of research in this area and highlight the need for well-designed clinical trials to define the role of brain stimulation in pain management. These investigators stated that future studies should address several questions (e.g., the duration of the effects, parameters of stimulation, and the use of medications). More importantly, sham-controlled trials on invasive brain stimulation for pain treatment should be carried out. This is in agreement with the observations of Fontaine et al (2009) who stated that studies with a better design are mandatory to confirm the effectiveness of MCS for the treatment of chronic neuropathic pain.

Plow and colleagues (2009) noted that residual motor deficits frequently linger after stroke. Search for newer effective strategies to promote functional recovery is ongoing. Brain stimulation, as a means of directing adaptive plasticity, is appealing. Animal studies and phase I and II trials in humans have indicated
safety, feasibility, and efficacy of combining rehabilitation and concurrent invasive cortical stimulation. However, a recent phase III trial showed no advantage of the combination. These researchers critically reviewed results of various trials and discussed the factors that contributed to the distinctive result. Regarding cortical stimulation, it is important to determine (i) the location of peri-infarct representations by integrating multiple neuro-anatomical and physiological techniques; (ii) the role of other mechanisms of stroke recovery; (iii) the viability of peri-infarct tissue and descending pathways; (iv) the lesion geometry to ensure no alteration/displacement of current density; and (v) the applicability of lessons generated from non-invasive brain stimulation studies in humans. In terms of combining stimulation with rehabilitation, the following points should be understood (i) the principle of homeostatic plasticity; (ii) the effect of ongoing cortical activity and phases of learning; and (iii) that subject-specific intervention may be necessary. The authors concluded that future cortical stimulation trials should consider the factors that may have contributed to the peculiar results of the phase III trial and address those in future study designs.

Lefaucheur et al (2009) presented the results of the first RCT using chronic MCS for the treatment of refractory peripheral neuropathic pain. A total of 16 patients were included with pain origin as follows: trigeminal neuralgia (n = 4), brachial plexus lesion (n = 4), neurofibromatosis type-1 (n = 3), upper limb amputation (n = 2), herpes zoster ophthalmicus (n = 1), atypical orofacial pain secondary to dental extraction (n = 1) and traumatic nerve trunk transection in a lower limb (n = 1). A quadripolar lead was implanted, under radiological and electrophysiological guidance, for epidural cortical stimulation. A randomized cross-over trial was performed between 1 and 3 months post-operative, during which the stimulator was alternatively switched “on” and “off” for 1 month, followed by an open phase during which the stimulator was switched "on" in all patients. Clinical assessment was performed up to 1 year after implantation and was based on the following evaluations: VAS, brief pain inventory, McGill Pain questionnaire, sickness impact profile and medication quantification scale. The cross-over trial included 13 patients and showed a reduction of the McGill Pain questionnaire-pain rating index (p = 0.0166, Wilcoxon test) and McGill Pain questionnaire sensory subscore (p = 0.01) when the stimulator was switched "on" compared to the "off-stimulation" condition. However, these differences did not persist after adjustment for multiple comparisons. In the 12 patients who completed the open study, the VAS and sickness impact profile scores varied significantly in the follow-up and were reduced at 9 to 12 months post-operative, compared to the pre-operative baseline. At final examination, the mean rate of pain relief on VAS scores was 48 % (individual results ranging from 0 % to 95 %) and MCS efficacy was considered as good or satisfactory in 60 % of the patients. Pain relief after 1 year tended to correlate with pain scores at 1 month post-operative, but not with age, pain duration or location, pre-operative pain scores or sensory-motor status. Although the results of the cross-over trial were slightly negative, which may have been due to carry-over effects from the operative and immediate post-operative phases, observations made during the open trial were in favor of a real efficacy of MCS in peripheral neuropathic pain. Analgesic effects were obtained on the sensory-discriminative rather than on the affective aspect of pain. The authors concluded that these findings suggested that the indication of MCS might be extended to
various types of refractory, chronic peripheral pain beyond TNP. The results of this small study needs to be validated by well-designed studies.

Anderson et al (2009) reported on a patient with a neuropathic facial pain syndrome, including elements of trigeminal neuralgia, glossopharyngeal neuralgia, and dysphagia. After failing medical and surgical decompressive treatments, the patient underwent implantation of a MCS system. The patient was a 54-year old woman who had a 14-year history of left-sided facial pain, throat pain, and associated nausea and vomiting. She failed several open surgical and percutaneous procedures for her facial pain syndrome. Additionally, several medication trial attempts were unsuccessful. Imaging studies were normal. The patient underwent placement of a right-sided MCS system for treatment of her neuropathic facial pain syndrome. The procedure was well-tolerated, and the trial stimulator provided promising results. The permanent MCS generator needed to be re-programmed at the time of the 5-week follow-up visit to optimize symptom relief. The patient demonstrated dramatic improvements in her neuropathic facial and oral pain, including improvements in swallowing toleration, after the 5-week follow-up examination with sub-threshold MCS. A decline in treatment efficacy also occurred 2 years after implantation due to generator depletion. Symptom improvement returned with stimulation after the generator was replaced. The authors concluded that a novel implantable MCS system was used to treat this patient's neuropathic facial pain. Durable improvements were noted not only in her facial pain, but also in swallowing toleration. The ultimate role of MCS in the treatment of pain conditions is still not well-defined but might play a part in refractory cases and, as in this case, might improve other functional issues, including dysphagia.

In a double-blind, placebo-controlled trial, Di Lazzaro and colleagues (2009) tested the hypothesis that repetitive transcranial magnetic stimulation given as continuous theta burst stimulation (cTBS), repeated monthly for 1 year, would affect amyotrophic lateral sclerosis (ALS) progression. A total of 20 patients with ALS were randomly allocated to blinded real or placebo stimulation. Continuous theta burst stimulation of the motor cortex was performed for 5 consecutive days every month for 1 year. Primary outcome was the rate of decline as evaluated with the revised ALS functional rating scale (ALSFRS-R). Treatment was well-tolerated. There was no significant difference in the ALSFRS-R score deterioration between patients treated with real or placebo stimulation. ALSFRS-R mean scores declined from 32.0 (SD 7.1) at study entry to 23.1 (SD 6.3) at 12 months in patients receiving real cTBS and from 31.3 (SD 6.9) to 21.2 (SD 6.0) in those receiving placebo stimulation. Although cTBS proved a safe procedure, on the basis of the present findings a larger randomized confirmatory trial seems unjustified in ALS patients, at least in advanced stage of the disease.

Central pain syndrome is a neurological condition caused by damage to or dysfunction of the central nervous system (CNS), which includes the brain, brainstem, and spinal cord. This syndrome can be caused by stroke, multiple sclerosis, tumors, epilepsy, brain or spinal cord trauma, or Parkinson’s disease. http://www.ninds.nih.gov/disorders/central_pain/central_pain.htm.

Moreno-Duarte et al (2014) reviewed initial efficacy, safety and potential predictors of response by assessing the effects of neural stimulation techniques to treat
spinal cord injury (SCI) pain. A literature search was performed using the PubMed database including studies using the following targeted stimulation strategies: transcranial direct current stimulation (tDCS), high-definition tDCS (HD-tDCS), repetitive transcranial magnetic stimulation (rTMS), cranial electrotherapy stimulation (CES), transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS) and MCS, published prior to June of 2012. These researchers included studies from 1998 to 2012. A total of 8 clinical trials and 1 naturalistic observational study (9 studies in total) met the inclusion criteria. Among the clinical trials, 3 studies assessed the effects of tDCS, 2 of CES, 2 of rTMS and 1 of TENS. The naturalistic study investigated the analgesic effects of SCS. No clinical trials for epidural MCS or HD-tDCS were found. Parameters of stimulation and also clinical characteristics varied significantly across studies. Three out of 8 studies showed larger effects sizes (0.73, 0.88 and 1.86, respectively) for pain reduction. Classical neuropathic pain symptoms such as dysesthesia (defined as an unpleasant burning sensation in response to touch), allodynia (pain due to a non-painful stimulus), pain in paroxysms, location of SCI in thoracic and lumbar segments and pain in the lower limbs seem to be associated with a positive response to neural stimulation. No significant adverse effects were reported in these studies. The authors concluded that chronic pain in SCI is disabling and resistant to common pharmacologic approaches. Electrical and magnetic neural stimulation techniques have been developed to offer a potential tool in the management of these patients. Although some of these techniques are associated with large standardized mean differences to reduce pain, these researchers found an important variability in these results across studies. The authors concluded that there is a clear need for the development of methods to decrease treatment variability and increase response to neural stimulation for pain treatment.

Bolognini et al (2013) stated that limb amputation may lead to chronic painful sensations referred to the absent limb, i.e., phantom limb pain (PLP), which is likely subtended by maladaptive plasticity. These researchers examined if tDCS, a non-invasive technique of brain stimulation that can modulate neuroplasticity, can reduce PLP. In 2 double-blind, sham-controlled experiments in subjects with unilateral lower or upper limb amputation, they measured the effects of a single session of tDCS (2 mA, 15 mins) of the primary motor cortex (M1) and of the posterior parietal cortex (PPC) on PLP, stump pain, non-painful phantom limb sensations and telescoping. Anodal tDCS of M1 induced a selective short-lasting decrease of PLP, whereas cathodal tDCS of PPC induced a selective short-lasting decrease of non-painful phantom sensations; stump pain and telescoping were not affected by parietal or by motor tDCS. These findings demonstrated that painful and non-painful phantom limb sensations are dissociable phenomena. Phantom limb pain is associated primarily with cortical excitability shifts in the sensorimotor network; increasing excitability in this system by anodal tDCS has an antalgic effect on PLP. Conversely, non-painful phantom sensations are associated to a hyper-excitation of PPC that can be normalized by cathodal tDCS. The authors concluded that this evidence highlighted the relationship between the level of excitability of different cortical areas, which underpins maladaptive plasticity following limb amputation and the phenomenology of phantom limb, and it opens up new opportunities for the use of tDCS in the treatment of PLP. Well-designed studies are needed to ascertain the effectiveness of MCS in the treatment of PLP.
Moore et al (2014) noted that chronic neuropathic pain affects 8.2% of adults, extrapolated to roughly 18 million people every year in the United States. Patients who have pain that cannot be controlled with pharmacologic management or less invasive techniques can be considered for deep brain stimulation or MCS. These techniques are not currently approved by the Food and Drug Administration for chronic pain and are, thus, considered off-label use of medical devices for this patient population. The authors stated that conclusive effectiveness studies are still needed to demonstrate the best targets as well as the reliability of the results with these approaches.

In a double-blind, cross-over, multi-center, pilot study, Rieu et al (2014) evaluated the effectiveness of epidural MCS on dystonia, spasticity, pain, and quality of life in patients with dystonia secondary to a focal basal ganglia (BG) lesion. A total of 5 patients with dystonia secondary to a focal BG lesion were included in this study. Two quadri-polar leads were implanted epidurally over the M1 and the premotor cortex, contralateral to the most dystonic side. The leads were placed parallel to the central sulcus. Only the posterior lead over M1 was activated in this study. The most lateral or medial contact of the lead (depending on whether the dystonia predominated in the upper or lower limb) was selected as the anode, and the other 3 as cathodes. One month post-operatively, patients were randomly assigned to on- or off-stimulation for 3 months each, with a 1-month washout between the 2 conditions. Voltage, frequency, and pulse width were fixed at 3.8 V, 40 Hz, and 60 μs, respectively. Evaluations of dystonia (Burke-Fahn-Marsden Scale), spasticity (Ashworth score), pain intensity (VAS), and quality of life (36-Item Short Form Health Survey) were performed before surgery and after each period of stimulation. Burke-Fahn-Marsden Scale, Ashworth score, pain intensity, and quality of life were not statistically significantly modified by MCS. The authors concluded that bipolar epidural MCS failed to improve any clinical feature in dystonia secondary to a focal BG lesion.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:

61850
61860
61885
61886
64573
95961
+ 95962
95970
Other CPT codes related to the CPB:

+61781
+61782
61880
61888
70551 -
70553
70554 -
70555
95927
95965 -
95967
96020

HCPCS codes not covered for indications listed in the CPB:

C1767  Generator, neurostimulator (implantable), nonrechargeable
C1770  Imaging coil, magnetic resonance (insertable)
C1778  Lead, neurostimulator (implantable)
C1787  Patient programmer, neurostimulator
C1816  Receiver and/or transmitter, neurostimulator (implantable)
C1820  Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1883  Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897  Lead, neurostimulator test kit (implantable)
E0745  Neuromuscular stimulator, electronic shock unit
L8680  Implantable neurostimulator electrode, each
L8681  Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682  Implantable neurostimulator radiofrequency receiver
L8683  Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685  Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686  Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689  External recharging system for battery (internal) for use with implantable neurostimulator
L8695  External recharging system for battery (external) for use with implantable neurostimulator

**ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):**

- 307.3  Stereotypic movement disorder
- 327.51  Periodic limb movement disorder
- 327.59  Other organic sleep related movement disorders
- 332.0 - 332.1  Parkinson's disease
- 333.0 - 333.99  Other extrapyramidal diseases and abnormal movement disorders
- 335.20  Amyotrophic lateral sclerosis
- 338.21 - 338.29  Chronic pain
- 338.3  Neoplasm related pain (acute) (chronic)
- 338.4  Chronic pain syndrome
- 350.1  Trigeminal neuralgia
- 438.20 - 438.22  Hemiplegia/hemiparesis, late effect of cerebrovascular disease
- 780.58  Sleep related movement disorder, unspecified
- 781.0  Abnormal involuntary movements
- 787.20  Dysphagia

The above policy is based on the following references:
