Subject: Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES)

Policy Number: NMP442

Effective Date*: November 2008

Updated: August 2016

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

For Medicaid Plans: Please refer to the appropriate State's Medicaid manual(s), publication(s), citations(s) and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

The Centers for Medicare & Medicaid Services (CMS)
For Medicare Advantage members please refer to the following for coverage guidelines first:

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<tr>
<th>Use</th>
<th>Source</th>
<th>Reference/Website Link</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>National Coverage Manual Citation</td>
<td></td>
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<tr>
<td></td>
<td>Local Coverage Determination (LCD)*</td>
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<td>Article (Local)*</td>
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Use Health Net Policy

Instructions

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement

A. Health Net, Inc. considers neuromuscular electrical stimulation (NMES) medically necessary for the treatment of disuse muscle atrophy, when both of the following criteria are met:

1. There is a non-neurological reasons for the disuse atrophy, such as any of the following:
   - Casting or splinting of a limb;
   - Contracture due to scarring of soft tissue as in burn lesions;
   - Following hip replacement surgery until physical therapy begins

   AND

2. Nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves.

Health Net, Inc. considers neuromuscular electrical stimulation (NMES) or functional electrical stimulation (FES) for any other indication, including, but not limited to the following, investigational:

1. Stroke-related muscle weakness or paralysis (e.g., wrist and finger function; prevention or correction of shoulder subluxation; treatment of swallowing disorders)
2. Improving motor function in patients with cerebral palsy, and

3. Providing exercise for patients with severe physical limitations due to chronic osteoarthritis, severe scoliosis or severe osteoporosis, obstructive pulmonary disease or chronic heart failure.

4. Improving motor function and/or for the treatment of spasticity in multiple sclerosis

Health Net, Inc. considers neuromuscular electrical stimulation (NMES) or functional electrical stimulation (FES) not medically necessary for the following indications:

1. Individuals with cardiac pacemakers

2. Skin disease or cancer at area of stimulation

3. Irreversible contracture

4. Autonomic dysflexia

B. Health Net, Inc. considers neuromuscular electrical stimulation (NMES) and functional electrical stimulation (FES) (e.g. Parastep I system), medically necessary to enhance the ability to walk in individuals with spinal cord injury (SCI) who meet all of the following characteristics:

1. Individuals with intact lower motor units (L1 and below) (both muscle and peripheral nerve);

2. Individuals with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;

3. Individuals that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;

4. Individuals that possess high motivation, commitment and cognitive ability to use such devices for walking;

5. Individuals that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;

6. Individuals that can demonstrate hand and finger function to manipulate controls;

7. Individuals with at least 6-month post recovery spinal cord injury and restorative surgery;

8. Individuals without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9. Individuals who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months; and

10. Individuals who have demonstrated a willingness to use the device long-term.
Abbreviations
NMES  Neuromuscular electrical stimulation
FES  Functional electrical stimulation
SCI  Spinal cord injury
ACL  Anterior cruciate ligament
OA  Osteoarthritis
CHF  Chronic heart failure
COPD  Chronic obstructive pulmonary disease
CP  Cerebral palsy
TES  Threshold electrical stimulation
EMG-NMES  EMG-triggered neuromuscular electrical stimulation
sNMES  Surface neuromuscular electrical stimulation
ARAT  Action Research Arm Test
MVIC  Maximum voluntary isometric contraction
CSA  Cross-sectional area
LLB  Long leg braces

Codes Related To This Policy
NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

ICD-9 Codes
728.0-728.9  Disorders of muscle, ligament, and fascia
806.00 - 806.69  Fracture of vertebral column with spinal cord injury
820  Hip fracture
906.60 906.7  Late effects of burns
907.2  Late effect of spinal cord injury
952.00 – 952.2  Spinal cord injury without evidence of spinal bone injury (cervical, thoracic, lumbar)

ICD-10 Codes
M62.40-M62.49  Contracture of muscle
M62.50-M62.59  Muscle wasting and atrophy, not elsewhere classified
M63.80-M63.89  Disorders in muscles not classified elsewhere
M70.031-M79.9  Other soft tissue disorder
S12.000-S14.109  Fracture of cervical vertebra and other parts of neck
S22.010-S24.159  Fracture of thoracic vertebra
S32.009-S32.059  Fracture of lumbar vertebra initial
S34.101-S34.139  Injury of lumbar and sacral spinal cord and nerves at abdomen, lower back (lumbar and sacral spinal cord and pelvis level
S72.001-S72.499  Fracture of head of neck and femur
T23.001-T23.779  Burn and corrosion of wrist and hand
T24.001-T24.799  Burn and corrosion of lower limb, except ankle and
T25.011-T25.799  Burn or corrosion of ankle and foot
T30.0-T32.99  Burns and corrosions of multiple and unspecified body regions
CPT Codes
64550 Application of surface (transcutaneous) neurostimulator
94014 Patient–initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and review and interpretation by a physician or other qualified health care professional
97032 Application of a modality to one or more areas; electrical stimulation (manual) each fifteen minutes
97110 Therapeutic procedure, one or more areas, each fifteen minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112 Therapeutic procedure, one or more areas, each fifteen minutes; neuromuscular reeducation of movement, balance, co-ordination, kinesthetic sense, posture, and /or proprioception for sitting and/or standing activities
97116 Therapeutic procedure, one or more areas, each fifteen Minutes; gait training (includes stair climbing)

HCPCS Codes
A4595 Electrical stimulator supplies, 2 lead, per month (e.g. TENS, NMES)
E0745 Neuromuscular stimulator, electronic shock unit
E0764 Functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0770 Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
G0283 Electrical stimulation unattended, to one or more areas for indication other than wound care, as part of a therapy plan of care

Scientific Rationale – Update August 2016
Cui et al (2016) investigated the effects of a 12-hour neuromuscular electrical stimulation program in the evening hours on upper extremity function in sub-acute stroke patients. Forty-five subjects were randomized to one of three groups: 12-hour neuromuscular electrical stimulation group (n=15), which received 12 hours of neuromuscular electrical stimulation and conventional rehabilitation for the affected upper extremity; neuromuscular electrical stimulation group (n=15), which received 30 min of neuromuscular electrical stimulation and conventional rehabilitation; and control group (n=15), which received conventional rehabilitation only. The Fugl-Meyer assessment, Action Research Arm Test, and modified Ashworth scale were used to evaluate the effects before and after intervention, and 4 weeks later. The improvement in the distal (wrist-hand) components of the Fugl-Meyer assessment and Action Research Arm Test in the 12-hour neuromuscular electrical stimulation group was more significant than that in the neuromuscular electrical stimulation group. No significant difference was found between the two groups in the proximal component (shoulder-elbow) of the Fugl-Meyer assessment. The authors concluded the 12-hour neuromuscular electrical stimulation group achieved better improvement in upper extremity motor function, especially in the wrist-hand function. This alternative therapeutic approach is easily applicable and can be used in stroke patients during rest or sleep.

Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16
Scientific Rationale – Update August 2015

Stein et al (2015) reported neuromuscular electric stimulation (NMES) has been used to reduce spasticity and improve range of motion in patients with stroke. However, contradictory results have been reported by clinical trials. A systematic review of randomized clinical trials was conducted to assess the effect of treatment with NMES with or without association to another therapy on spastic muscles after stroke compared with placebo or another intervention. The authors searched the following electronic databases (from inception to February 2015): Medline (PubMed), EMBASE, Cochrane Central Register of Controlled Trials and Physiotherapy Evidence Database (PEDro). Two independent reviewers assessed the eligibility of studies based on predefined inclusion criteria (application of electric stimulation on the lower or upper extremities, regardless of NMES dosage, and comparison with a control group which was not exposed to electric stimulation), excluding studies with <3 days of intervention. The primary outcome extracted was spasticity, assessed by the Modified Ashworth Scale, and the secondary outcome extracted was range of motion, assessed by Goniometer. Of the total of 5066 titles, 29 randomized clinical trials were included with 940 subjects. NMES provided reductions in spasticity (-0.30 [95% confidence interval, -0.58 to -0.03], n=14 randomized clinical trials) and increase in range of motion when compared with control group (2.87 [95% confidence interval, 1.18-4.56], n=13 randomized clinical trials) after stroke. The reviewers concluded NMES combined with other intervention modalities can be considered as a treatment option that provides improvements in spasticity and range of motion in patients after stroke.

Karabay et al (2014) explored the short-term effects of NMES application on tibialis anterior (stimulated muscle) and gastrocnemius (antagonist) muscles' size and architecture in children with cerebral palsy by using ultrasound. This prospective, controlled study included 28 children diagnosed with spastic diplegic cerebral palsy. Participants were treated either with NMES application and conventional physiotherapy (group A) or with conventional physiotherapy alone (group B). Outcome was evaluated by clinical (gross motor function, selective motor control, range of motion, spasticity) and ultrasonographic (cross-sectional area, pennation angle, fascicle length of tibialis anterior and gastrocnemius muscles) measurements before and after treatment in both groups. Cross-sectional area values of tibialis anterior (238.7 ± 61.5 vs. 282.0 ± 67.1 mm) and gastrocnemius (207.9 ± 48.0 vs. 229.5 ± 52.4 mm) (P < 0.001 and P = 0.008, respectively) muscles were increased after treatment in group A. Cross-sectional area values of tibialis anterior muscle were decreased (257.3 ± 64.7 vs. 239.7 ± 60.0 mm) after treatment in group B (P < 0.001), and the rest of the measurements were found not to have changed significantly in either group. The authors concluded the results have shown that cross-sectional area of both the agonist and antagonist muscles increased after 20 sessions of NMES treatment. Future studies with larger samples and longer follow-up are definitely awaited for better evaluation of NMES application on muscle architecture and its possible correlates in clinical/functional outcome.

Yıldızgören et al (2014) evaluated the effects of NMES on wrist range of motion, wrist and finger flexor spasticity, and hand functions in patients with unilateral cerebral palsy. Twenty-four children with unilateral spastic cerebral palsy (14 boys and 10 girls) between the ages of 5 and 14 years were randomized into NMES and control groups. Conventional exercises were applied, and static volar wrist-hand orthosis was administered to all patients 5 days a week for 6 weeks. Additionally, 30-minute neuromuscular electrical stimulation sessions were applied to the wrist extensor muscles in the neuromuscular electrical stimulation group. Patients were evaluated by Zancolli Classification System, Manual Ability Classification System, and Abilhand-Kids Test. Compared with baseline, a significant increase was evident in...
active wrist extension angle at the fourth and sixth weeks in both groups (all $P < 0.001$), more prominent in the NMES group at the fourth and sixth weeks ($P = 0.015$ and $P = 0.006$, respectively). A decrease was observed in the spasticity values in the NMES group at the fourth and sixth weeks ($P = 0.002$ and $P = 0.001$, respectively) and in the control group only at the sixth week ($P = 0.008$). Abilhand-Kids values improved only in the NMES group ($P < 0.001$). The authors concluded NMES application in addition to conventional treatments is effective in improving active wrist range of motion, spasticity, and hand functions in cerebral palsy.

**Scientific Rationale Update – August 2012**

Lin et al. (2011) completed a study to investigate the long-term efficacy of neuromuscular electrical stimulation in enhancing motor recovery in the upper extremities of stroke patients. A total of 46 patients with stroke were assigned to a neuromuscular electrical stimulation group or a control group. All patients received a standard rehabilitation programme. Patients in the neuromuscular electrical stimulation group received neuromuscular electrical stimulation for 30 min, 5 days a week for 3 weeks. Measurements were recorded before treatment, at the 2nd and 3rd week of treatment and 1, 3 and 6 months after treatment ended. The Modified Ashworth Scale for spasticity, the upper extremity section of the Fugl-Meyer motor assessment, and the Modified Barthel Index were used to assess the results. Significant improvements were found in both groups in terms of Fugl-Meyer motor assessment, and Modified Ashworth Scale scores after the 3rd week of treatment. The significant improvements persisted 1 month after treatment had been discontinued. At 3 and 6 months after treatment was discontinued the average scores in the neuromuscular electrical stimulation group were significantly better than those in the control group. Three weeks of neuromuscular electrical stimulation to the affected upper extremity of patients with stroke improves motor recovery. The effect persists for at least 6 months.

Broekmans et al. (2011) Resistance training studies in multiple sclerosis (MS) often use short intervention periods. The objective of this RCT involving 36 individuals is to examine the effect(s) of unilateral long-term (20 weeks) standardized resistance training with and without simultaneous electro-stimulation on leg muscle strength and overall functional mobility. At baseline (PRE) and after 10 (MID) and 20 (POST) weeks of standardized (ACSM) light to moderately intense unilateral leg resistance training (RES(O), $n = 11$) only or resistance training with simultaneous electro-stimulation (RES(E), $n = 11$, 100 Hz, biphasic symmetrical wave, 400 µs), maximal isometric strength of the knee extensors and flexors (45°, 90° knee angle) and dynamic (60-180°/s) knee-extensor strength was measured and compared with a control group (CON, $n = 14$). Functional mobility was evaluated using the Timed Get Up and Go, Timed 25 Foot Walk, Two-Minute Walk Test, Functional Reach and Rivermead Mobility Index. Maximal isometric knee extensor (90°, MID: +10 ± 3%, POST: +10 ± 4%) in RES(O) and knee flexor (45°, POST: +7 ± 4%; 90°, POST: +9 ± 5%) in RES(E) strength increased ($p < 0.05$) compared with CON but RES(O) and RES(E) did not differ. Also, impaired legs responded positively to resistance training (unilateral leg strength analysis) and functional reaching increased significantly in RES(O) (+18%) compared with CON. Dynamic muscle strength and the remaining functional mobility tests did not change. Long-term light to moderately intense resistance training improves muscle strength in persons with MS but simultaneous electro-stimulation does not further improve training outcome.

Miller et al. (2012) Electrical stimulation has been used in an effort to increase muscle strength in children with cerebral palsy. In neuromuscular electrical stimulation (NMES), electrical impulses of high intensity and short duration generate muscle contraction. In threshold electrical stimulation (TES), the stimulus is of lower
intensity and does not generate muscle contraction; it is typically applied during sleep. While these approaches are appealing, several randomized trials have failed to show clinically significant improvement in muscle strength or function of cerebral palsy patients, although the numbers are small in these studies.

**Scientific Rationale Update – September 2011**

Lin et al (2011) investigated the long-term efficacy of neuromuscular electrical stimulation (NEMS) in enhancing motor recovery in the upper extremities of 46 stroke patients. Patients with stroke were assigned to a NEMS group or a control group. All patients received a standard rehabilitation program. Patients in the NEMS group received NEMS for 30 min, 5 days a week for 3 weeks. Measurements were recorded before treatment, at the 2nd and 3rd week of treatment and 1, 3 and 6 months after treatment ended. The Modified Ashworth Scale for spasticity, the upper extremity section of the Fugl-Meyer motor assessment, and the Modified Barthel Index were used to assess the results. Significant improvements were found in both groups in terms of Fugl-Meyer motor assessment, and Modified Ashworth Scale scores after the 3rd week of treatment. The significant improvements persisted 1 month after treatment had been discontinued. At 3 and 6 months after treatment was discontinued the average scores in the NEMS group were significantly better than those in the control group. The investigators concluded three weeks of NEMS to the affected upper extremity of patients with stroke improves motor recovery. The effect persists for at least 6 months.

Sentandreu et al (2011) examined the effect of an electrostimulation protocol on range of motion and strength of the hand in a group of elderly patients with spastic hemiplegia after a stroke. 20 elderly patients 60 years old and over with hand impairment due to stroke were randomly assigned to either the experimental group (conventional rehabilitation and NEMS) or control group (conventional rehabilitation). NMES was applied on wrist and finger extensors 30min 3 days/week for 8 weeks. Outcome measurements included goniometry and dynamometry tests. The patients were evaluated at baseline, after 4 and 8 weeks of treatment. After the treatment, the experimental group showed significant improvements (p<0.05) in range of motion: resting wrist angle, active wrist extension, passive wrist extension and resting metacarpophalangeal angle of fingers; and strength of hand: grip and pinch strength. Investigators concluded the observed changes seem to be associated with the presence of intervention and they suggest that the NMES protocol applied could be a useful complementary rehabilitation treatment to improve hand motor impairment in carefully selected patients after a stroke.

Chang et al (2011) investigated the effect of 8 weeks of surface functional electrical stimulation (FES) training on the levels of general, central, and peripheral fatigue in MS patients. Seven of nine individuals with MS (average age: 42.86 +/- 13.47 years) completed 8 weeks of quadriceps muscle surface FES training. Maximal voluntary contraction, voluntary activation level, twitch force, General Fatigue Index (FI), Central Fatigue Index (CFI), Peripheral Fatigue Index, and Modified Fatigue Impact Scale (MFIS) scores were determined before and after training. The results showed that FI (p = 0.01), CFI (p = 0.02), and MFIS (p = 0.02) scores improved significantly after training. Improvements in central fatigue contributed significantly to improvements in general fatigue (p < 0.01). The investigators concluded the results of the current study showed that central fatigue was a primary limitation in patients with MS during voluntary exercise and that 8 weeks of surface FES training for individuals with MS led to significantly reduced fatigue, particularly central fatigue.
**Scientific Rationale Update - November 2010**

Broderick et al. (2010) completed a study to determine if patient comfort and tolerance of NMES was affected by applying stimulation in proximity to an orthopaedic implant. There was a concern that this may cause a concentration of current around the metal which could result in hypersensitivity of NMES and reduce its effectiveness. Twenty patients took part in this study, 10 total hip and 10 total knee arthroplasty patients. Each patient was at least 3 weeks post surgery. NMES was applied to the calf muscles of each leg using skin surface electrodes. Four excitatory levels were recorded, which were: sensory threshold, motor threshold, pain threshold and pain tolerance. Following this, patients underwent a 5min stimulation session and indicated their overall comfort level on a visual analogue scale. Measurements of peak venous velocity, mean velocity and volume flow were recorded by duplex scanning from the popliteal vein at rest and in response to NMES elicited contractions during this session. Finally, patients completed a short verbal interview detailing their experience with the NMES treatment. The blood flow results showed increases in peak venous velocities, mean velocities and volume flow produced by NMES of 200%, 60% and 60% respectively when compared to resting blood flow. Comfort assessment indicated that the presence of a metallic implant did not give rise to hypersensitivity due to NMES. Patients found the application of calf muscle NMES comfortable and acceptable as a treatment. This study noted that the use of NMES on postoperative orthopaedic patients might be safely administered as a DVT prevention method, however additional larger, randomized controlled or comparison studies are necessary, to determine the safety, efficacy and long-term outcomes of this procedure.

**Scientific Rationale Update – May 2010**

Multiple sclerosis is an inflammatory demyelinating disease of the central nervous system. This diverse disease results in injury to the myelin sheath (the fatty matter that covers the axons of the nerve cells), the oligodendrocytes (the cells that produce myelin) and, to a lesser extent, the axons and nerve cells themselves. The symptoms of multiple sclerosis vary and each individual will experience different combinations of symptoms with differing severity, depending in part on the location of plaques (areas of thick scar tissue) within the central nervous system. Common symptoms include weakness and fatigue, sensory disturbances in the limbs, bladder or bowel dysfunction, problems with sexual function, and ataxia (loss of coordination).

Multiple, or disseminated, sclerosis (MS) is a slowly progressive disease of the central nervous system (CNS), that comprises the brain and spinal cord. The primary characteristic of MS is the destruction of myelin, a fatty insulation covering the nerve fibers. The end results of this process, called demyelination, are multiple patches of hard, scarred tissue called plaques. Another important feature in the disease is destruction of axons, the long filaments that carry electric impulses away from a nerve cell, which is now considered to be a major factor in the permanent disability that occurs with MS. Multiple sclerosis is usually characterized by a relapsing remitting course in the early stages, with full or nearly full recovery initially. In the early stages, there may be little damage to axons. Over time, the disease enters an irreversible progressive phase of neurological deficit. Each relapse causes further loss of nervous tissue and progressive dysfunction. In some cases there may be chronic progression without remission or acute disease rapidly leading to death.

This policy is based on the Medicare National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12). Per this Medicare NCD, the type of NMES that is used to enhance the ability to walk of spinal cord injury (SCI) patients is commonly referred to as functional electrical stimulation (FES). These
devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence, and not specifically noted as Walk Aids. There is no notation within this Medicare NCD that multiple sclerosis is currently a diagnose that would be covered by NMES.

However, there is a specific WalkAide which may be appropriate in the future for individuals with multiple sclerosis, however further studies are needed. Individuals with stroke, CP, multiple sclerosis, and spinal cord injury or traumatic brain injury may exhibit foot drop, a condition caused by weakness or paralysis of the muscles involved in lifting the front part of the foot. The WalkAide is a product of Myo-Orthotics Technology; the manufacturer is Innovative Neurotronics (Austin, TX). According to the manufacturer, this device represents the union of orthotic technology (which braces a limb) and electrical stimulation (which restores specific muscle function). The WalkAide device is intended to counteract foot drop by producing dorsiflexion of the ankle during the swing phase of the gait.

The device attaches to the leg, just below the knee, near the head of the fibula. During a gait cycle, the WalkAide stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that produce dorsiflexion of the ankle. The WalkAide is designed to offer persons with foot drop increased mobility, functionality and independence. It was cleared by the FDA through the 510(k) process on September 21, 2005. However, there is currently insufficient evidence to support its use for foot drop and other indications. Prospective clinical studies of the WalkAide device are necessary to evaluate whether it improves function and reduces disability compared to standard bracing in persons with foot drop.

Per The International Standards for Neurological and Functional Classification of Spinal Cord Injury, a spinal cord injury (SCI) is an insult to the spinal cord resulting in a change, either temporary or permanent, in its normal motor, sensory, or autonomic function. This International Classification of Spinal Cord Injury, is a widely accepted system describing the level and extent of injury based on a systematic motor and sensory examination of neurologic function. Per this classification system, the following terminology has developed around the classification of SCI:

- Tetraplegia (replaces the term quadriplegia) - Injury to the spinal cord in the cervical region, with associated loss of muscle strength in all 4 extremities
- Paraplegia - Injury in the spinal cord in the thoracic, lumbar, or sacral segments, including the cauda equina and conus medullaris.

In the evaluation of the literature regarding the use of electrical stimulation for the treatment of spasticity in multiple sclerosis, the Multiple Sclerosis Council for Clinical Practice Guidelines (2005) states that surface electrical stimulation may be of benefit in reducing spasticity in persons with MS, but there is currently no evidence to support this supposition at this time.

Additional randomized controlled trials have investigated the use of FES in multiple sclerosis (n=24) (Paul, et al., 2008), cerebral palsy (n=14) (van der Linden, et al., 2008), and chronic heart failure (n=30) (Karavidas, et al., 2009). Although the results of these studies suggested that FES had a beneficial effect, the authors agreed that additional, larger trials were needed to support the outcomes.

**Scientific Rationale – Initial**

Neuromuscular electrical stimulation (NMES) is a technique that involves the use of transcutaneous application of electrical currents to cause muscle contractions, to prevent or retard disuse atrophy, to relax muscle spasms, and to promote voluntary

Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16
Neuromuscular electrical stimulation (NMES) and Functional Electrical Stimulation (FES) is used to control the muscles in individuals who have lost muscle function due to surgery, neurological injury, or disabling condition. NMES is generally divided into two categories: NMES that stimulates muscle when the patient is in a resting state to treat muscle atrophy and NMES used to enhance functional activity of neurologically impaired patients, commonly referred to as functional electrical stimulation (FES).

**Neuromuscular electrical stimulation (NMES)**

NMES has been investigated for the treatment of a variety of indications, including but not limited to, the prevention of shoulder subluxation after stroke-related paralysis; regaining wrist or swallowing function after partial paralysis due to stroke or spinal cord injury; strengthening leg muscles after hip fracture, hip replacement, total knee arthroplasty or surgical repair of the anterior cruciate ligament (ACL); treatment of muscle atrophy and weakness in individuals with rheumatoid arthritis; Bell’s Palsy; providing exercise for individuals with severe physical limitations due to osteoarthritis (OA), chronic heart failure (CHF), or chronic obstructive pulmonary disease (COPD); and improving motor function in patients with cerebral palsy (CP).

NMES can be performed at low, medium, or high intensity to elicit mild, moderate, or strong muscle contractions. Threshold electrical stimulation (TES) or threshold NMES refers to the NMES techniques used at very low intensity. High-intensity NMES is applied for short periods of time (i.e., 30-60 minutes per day) to avoid muscle strain, while slow intensity and TES can be applied for longer periods of time. NMES is usually used in conjunction with physical and occupational therapy. Individuals are also encouraged to voluntarily exercise the affected muscle to improve strength and function.

Although the evidence is limited, NMES for the treatment of disuse atrophy in patients where the nerve supply to the muscle is intact appears to be considered standard of care. There is some evidence that the use of NMES may be an effective rehabilitative regimen to prevent muscle atrophy associated with prolonged knee immobilization following ligament reconstruction surgery or injury, however, controlled clinical trials are necessary to determine if the addition of NMES to the rehabilitation program following TKA improve health outcomes. There are numerous clinical trials underway and actively recruiting to investigating the use of NMES for a variety of indications.

Bax et al (2005) performed a systematic review and meta-analysis of randomized controlled trials to determine whether NMES is an effective modality for strength augmentation of the quadriceps femoris. Thirty-five trials were included and evaluated although the reviewer reported that the included trials were generally of poor quality and meta-analytic data indicate that publication bias may be present. The reviewer found that the evaluated data suggested that, both for the unimpaired and impaired quadriceps, NMES makes sense compared with doing no exercises but volitional exercises appear to be more effective in most situations. The reviewer concluded that based on the available evidence, NMES may only be preferred over volitional training for within-cast muscle training and perhaps in specific situations where volitional training does not receive sufficient patient compliance.

In a randomized, double blind, controlled trial, Paternostro-Sluga et al (1999) investigated the effectiveness of NMES of the knee extensor and flexor muscles in the prevention of muscular weakening after anterior cruciate ligament surgery (ACL). Forty-nine patients after ACL surgery were assigned randomly either to a NMES and exercise group, a transcutaneous electrical nerve stimulation as analgesic and exercise group, or an exercise alone group as control. All groups received a standard regimen of rehabilitation after ACL surgery. Te NMES and transcutaneous electrical nerve stimulation group additionally received electrical stimulation during the first 6 weeks.
weeks after surgery. Patients were measured for isometric and isokinetic torque in the knee extensor and flexor muscles after 6, 12, and 52 weeks. No statistical difference among groups was observed. The investigator concluded that neuromuscular electrical stimulation in combination with an early exercise therapy regimen is not significantly more effective in reducing weakening than an early exercise therapy regimen alone after anterior cruciate ligament surgery.

Lake et al (1992) reports in its comprehensive review that NMES has been used for muscle strengthening, maintenance of muscle mass and strength during prolonged periods of immobilization, selective muscle retraining, and the control of edema. He reports that several investigators have reported increased isometric muscle strength in both NMES-stimulated and exercise-trained healthy, young adults when compared to unexercised controls, and also no significant differences between the NMES and voluntary exercise groups. He also notes that it appears that when NMES and voluntary exercise are combined there is no significant difference in muscle strength after training when compared to either NMES or voluntary exercise alone. The author reports that there is evidence that NMES can improve functional performance in a variety of strength tasks. The author suggested two mechanisms explain the training effects seen with NMES. The first mechanism proposes that augmentation of muscle strength with NMES occurs in a similar manner to augmentation of muscle strength with voluntary exercise. This mechanism would require NMES strengthening protocols to follow standard strengthening protocols that call for a low number of repetitions with high external loads and a high intensity of muscle contraction. The second mechanism proposes that the muscle strengthening seen following NMES training results from a reversal of voluntary recruitment order with a selective augmentation of type II muscle fibers. Because type II fibers have a higher specific force than type I fibers, selective augmentation of type II muscle fibers will increase the overall strength of the muscle. The use of neuromuscular electrical stimulation to prevent muscle atrophy associated with prolonged knee immobilization following ligament reconstruction surgery or injury has been extensively studied. NMES has been shown to be effective in preventing the decreases in muscle strength, muscle mass and the oxidative capacity of thigh muscles following knee immobilization. In all but one of the studies, NMES was shown to be superior in preventing the atrophic changes of knee immobilization when compared to no exercise, isometric exercise of the quadriceps femoris muscle group, isometric co-contraction of both the hamstrings and quadriceps femoris muscle groups, and combined NMES-isometric exercise. It has also been reported that NMES applied to the thigh musculature during knee immobilization improves the performance on functional tasks.

**NMES following Stroke**

Meilink et al (2008) performed a review of randomized controlled trials of EMG-triggered neuromuscular electrical stimulation (EMG-NMES) applied to the extensor muscles of the forearm after stroke. The author reported that no statistically significant differences in effects were found between and usual care. They noted that most studies had poor methodological quality, low statistical power and insufficient treatment contrast between experimental and control groups. In addition, all studies except two investigated the effects of EMG-NMES in the chronic phase after stroke, whereas the literature suggests that an early start, within the time window in which functional outcome of the upper limb is not fully defined, is more appropriate.

Church et al (2006) investigated one hundred seventy-six patients, within 10 days of stroke onset, randomized to receive surface neuromuscular electrical stimulation (sNMES) or placebo in addition to stroke unit care. The primary outcome measure was upper limb function measured by the Action Research Arm Test (ARAT) 3 months after stroke. Secondary outcome measures included other measures of upper limb function, upper limb impairment, pain, disability, and global health status. Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16
Outcome assessments were blinded. The investigator reported no difference in arm function between groups in terms of the primary outcome measure. The median ARAT at 3 months was 50 in the intervention group and 55.5 in the control group. Significant differences were seen at 3 months in favor of the control group for other measures of arm function and impairment: grasp and gross movement subsections of the ARAT, Frenchay Arm Test, and the arm subsection of the Motricity Index. Secondary analysis suggested that these differences were most marked in subjects with severe initial upper limb weakness. The author concluded that routine use of sNMES to the proximal affected upper limb after acute stroke cannot be recommended.

A randomized trial reported by Chae et al (2005) assessed the effectiveness of intramuscular electrical stimulation at 12 months post-treatment in 61 chronic stroke survivors with shoulder pain and subluxation. Treatment subjects received intramuscular electrical stimulation to the supraspinatus, posterior deltoid, middle deltoid, and upper trapezius for 6 hrs/day for 6 wks. Control subjects were treated with a cuff-type sling for 6 wks. Brief Pain Inventory question 12, an 11-point numeric rating scale was administered in a blinded manner at baseline, end of treatment, and at 3, 6, and 12 mos posttreatment. Treatment success was defined as a minimum 2-point reduction in Brief Pain Inventory question 12 at all posttreatment assessments. Secondary measures included pain-related quality of life (Brief Pain Inventory question 23), subluxation, motor impairment, range of motion, spasticity, and activity limitation. The investigator reported that the electrical stimulation group exhibited a significantly higher success rate than controls (63% vs. 21%). Repeated-measure analysis of variance revealed significant treatment effects on posttreatment Brief Pain Inventory question 12 and Brief Pain Inventory question 23. Treatment effects on other secondary measures were not significant.

Chantriane et al (1999) also investigated the effects of FES on subluxation and shoulder pain in one hundred twenty hemiplegic patients for 24 months' duration beginning in the first month after onset of stroke. All subjects received conventional rehabilitation and in addition, patients were alternately assigned to a control group or to receive additional FES for 5 weeks on muscles surrounding their subluxed and painful shoulder. Clinical examinations, including range of motion, pain assessment, and x-rays, were performed at the start of the study, between the second and fourth weeks after onset of stroke, and subsequently at 6, 12, and 24 months. The investigator reported the FES group showed significantly more improvement than the control group in both pain relief (80.7% vs. 55.1%) and reduction of subluxation (78.9% vs. 58.6%). Furthermore, recovery of arm motion appeared to be significantly improved in the FES group (77.1% vs. 60.3% in the control group).

NMES for Cerebral Palsy
van der Linden et al (2008) assessed the functional electrical stimulation (FES) of the ankle dorsiflexors and quadriceps in fourteen children with cerebral palsy (CP). Each child was randomly allocated to a treatment or control group. The treatment group received 2 weeks of neuromuscular electrical stimulation followed by 8 weeks of FES used at home and school. The control group continued with its usual physiotherapy program. Assessment took place at baseline and before and after the treatment period. Both control and treatment groups were fitted with FES for gait analysis at the second and final assessments. The investigator reported that in both groups, FES of the ankle dorsiflexors resulted in a significant effect on gait kinematics. However, no long-term treatment effect of using FES for 8 weeks was found.

Stackhouse et al (2007) investigated if isometric NMES or volitional training in children with CP could increase muscle strength and walking speed and examined the Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16.
mechanisms that may contribute to increased force production. Eleven children with spastic diplegia were assigned to an NMES training group or to a volitional training group. Participants in the NMES group had electrodes implanted percutaneously to activate the quadriceps femoris and triceps surae muscles. The volitional group trained with maximal effort contractions. Both groups performed a 12-week isometric strength-training program. Maximum voluntary isometric contraction (MVIC) force, voluntary muscle activation, quadriceps and triceps surae cross-sectional area (CSA), and walking speed were measured pre- and post-strength training. The investigator reported that the NMES-trained group had greater increases in normalized force production for both the quadriceps femoris and triceps surae. Similarly, only the NMES group showed an increase in walking speed after training. Changes in voluntary muscle activation explained approximately 67% and 37% of the changes seen in the MVIC of the NMES and volitional groups, respectively. Quadriceps femoris maximum CSA increased significantly for the NMES group only.

Kerr et al (2006) investigated the efficacy of NMES and threshold electrical stimulation (TES) in strengthening the quadriceps muscles of both legs in sixty children with CP in a randomized placebo-controlled trial. Children were randomized to one of the following groups: NMES (n=18), TES (n=20), or placebo (n=22). Clinical presentations were diplegia (n=55), quadriplegia (n=1), dystonia (n=1), ataxia (n=1), and non-classifiable CP (n=2). Thirty-four children walked unaided, 17 used posterior walkers, six used crutches, and the remaining three used sticks for mobility. Peak torque of the left and right quadriceps muscles, gross motor function, and impact of disability were assessed at baseline and end of treatment (16wks), and at a 6-week follow-up visit. The investigators reported that no statistically significant difference was demonstrated between NMES or TES versus placebo for strength or function. Statistically significant differences were observed between NMES and TES versus placebo for impact of disability at the end of treatment, but only between TES and placebo at the 6-week follow-up. The investigator concluded that further evidence is required to show whether NMES and/or TES may be useful as an adjunct to therapy in ambulatory children with diplegia who find resistive strengthening programs difficult.

Functional Electrical Stimulation (FES) for Walking in Patients with Spinal Cord Injury

The type of NMES that is use to enhance the ability to walk of spinal cord injury (SCI) patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence in an attempt to prevent or reverse muscular atrophy and bone demineralization by stimulating paralyzed lower limbs to perform stationary exercise or standing and walking. FES enables spinal cord injured individuals the ability to attain limited ambulation, however, it is not a replacement for a wheelchair.

According to the manufacturer (Sigmedics, Inc), the Parastep I system is a microcomputer controlled functional neuromuscular stimulation (FNS) system that enables independent, unbraced ambulation (i.e., standing and walking) by individuals with a spinal cord injury. The Parastep stimulator generates sequences of electrical pulses that are passed to target peripheral nerves through surface applied skin electrodes, placed over selected muscles and sensory nerves of the lower extremities. Stimulation of the quadriceps muscles causes a contraction, which results in knee extension, enabling the user to stand. Stimulation of sensory nerves in the lower extremities initiates a reflex contraction to flex the hip, knee, and ankle, lifting the foot off the floor; quadriceps stimulation then cycles on, to extend the knee in preparation for taking a step. The user controls stimulation through a user-friendly keypad on the stimulator unit or via control switches mounted on the

Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16
Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 1

Per the manufacturer, the Parastep System, when used in an approved program of long-term spinal cord injury management, will enable the individual to stand and walk short distances. Physical therapy, a key component of the Parastep, should include thirty-two sessions that include instruction on system use and gait training and are provided to users when they purchase a system. This training is provided by hospital-based physical therapists that have completed Sigmedics, Inc.’s clinical training program.

Guest et al (1997) investigated 12 men and 3 women with SCI paraplegia, to determine if participation in an electrical stimulation walking program experienced changes in measures of physical self-concept and depression after thirty-two FES ambulation training sessions using Parastep 1. The investigator reported that subsequent to the ambulation training program there were statistically significant increases in physical self-concept scores and decreases in depression scores.

Graupe and Kohn (1998) reported that approximately 400 patients have used the Parastep system, essentially all achieving standing and at least 30 feet of ambulation, with a few reaching as much as 1 mile at a time. They note that recent literature presents data on the medical benefits of using the Parastep system—beyond the exercise benefits of short distance ambulation at will—such as increased blood flow to the lower extremities, lower HR at subpeak work intensities, increased peak work capability, reduced spasticity, and psychological benefits.

Bonaroti et al (1999) prospectively compared functional electrical stimulation (FES) to long leg braces (LLB) as a means of upright mobility for five children with motor-complete thoracic level spinal cord injuries (SCIs). The hip and knee extensors were excitable by electrical stimulation. The authors reported that the FES system generally provided equal or greater independence in seven mobility activities as compared with LLB, provided faster sit-to-stand times, and was preferred over LLB in a majority of cases. They recommended follow-up evaluations of both modes of upright mobility to compare long-term performance and satisfaction.

Klose et al (1997) described performance parameters and effects on anthropometric measures in spinal cord injured subjects training with the Parastep 1 system. Thirteen men and 3 women with thoracic (T4-T11) motor-complete spinal cord injury: mean age, 28.8 yrs; mean duration postinjury, 3.8yrs underwent thirty-two functional neuromuscular stimulation ambulation training sessions using a commercially available system (Parastep-1). The authors reported that statistically significant changes in distance, time standing and walking, and pace were found. Increases in thigh and calf girth, thigh cross-sectional area, and calculated lean tissue, as well as a decrease in thigh skinfold measure, were all statistically significant. They concluded that the Parastep 1 system enables persons with thoracic-level spinal cord injuries to stand and ambulate short distances but with a high degree of performance variability across individuals. The factors that influence this variability have not been completely identified.

Gallien et al (1995) reported the results of functional electrical stimulation for the ambulation of paraplegic patients without long leg braces (LLB), according to the Parastep approach. Of 13 SCI patients with complete neurological lesions included in this trial, 12 progressed to independent ambulation with the aid of the Parastep. The average walking distance was 76 m, with a maximum of 350 m, and the mean speed 0.2 m s⁻¹. From this experience, it is concluded that this method is valuable for the...
Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16

restoration of standing and walking in the long-term management of spinal cord injury patients.

**Review History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>November 2008</td>
<td>Medical Advisory Council, initial approval</td>
</tr>
<tr>
<td>February 2009</td>
<td>Added HCPCS Code E0770 to the policy as a result of an inquiry. Functional electrical stimulation or electromagnetic wound treatment device, not otherwise classified</td>
</tr>
<tr>
<td>May 2010</td>
<td>Update. Added MS as not medically necessary. Codes reviewed.</td>
</tr>
<tr>
<td>November 2010</td>
<td>Added Medicare Table with Link to NCD. The Medical Advisory Council agreed to separate Commercial and Medicare Criteria. Added additional Not Medically Necessary criteria to ‘Commercial Policy Statement’ to be more in accordance with the Medicare NCD.</td>
</tr>
<tr>
<td>September 2011</td>
<td>Update – no revisions</td>
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<tr>
<td>August 2012</td>
<td>Update – no revisions</td>
</tr>
<tr>
<td>August 2015</td>
<td>Update – no revisions</td>
</tr>
<tr>
<td>August 2016</td>
<td>Update – no revisions</td>
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</tbody>
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**This policy is based on the following evidence-based guidelines:**


**References – Update August 2016**


Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16


References – Update August 2015


References – Update August 2014


Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16
References – Update August 2013

References – Update August 2012

References – Update September 2011

References Update November 2010

Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16

References Update May 2010

References Initial

Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16


28. Snyder-Mackler L, Ladin Z, Schepsis AA, Young JC. Electrical stimulation of the thigh muscles after reconstruction of the anterior cruciate ligament. Effects of electrically elicited contraction of the quadriceps femoris and hamstring muscles

Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16


32. Sigmedics, Inc. The Parastep I system.


Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) Aug 16
Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the Member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The Member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the Member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the Member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member’s Contract Controls Coverage Determinations.
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body.
caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

(1) To improve function or
(2) To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.