Subject: Dorsal Column Stimulators

Policy Number: NMP23

Effective Date*: September 2003

Updated: January 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), citation(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:

<table>
<thead>
<tr>
<th>Use</th>
<th>Source</th>
<th>Reference/Website Link</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>National Coverage Manual Citation</td>
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<tr>
<td></td>
<td>Local Coverage Determination (LCD)*</td>
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<tr>
<td></td>
<td>Article (Local)*</td>
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<tr>
<td></td>
<td>Other</td>
<td></td>
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<tr>
<td></td>
<td>None</td>
<td>Use Health Net Policy</td>
</tr>
</tbody>
</table>

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**
Health Net, Inc. considers dorsal column stimulation (DCS) medically necessary when all of the following are met:

1. The implantation of the stimulator is used only as a last resort for patients with chronic intractable pain;
2. Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
3. Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation of temporary electrodes. Such screening must include a physical evaluation, as well as a face-to-face psychiatric/psychological evaluation conducted by a licensed psychiatrist, psychologist or other licensed mental health professional who has a working knowledge of the psychological issues involved in chronic pain syndromes; and
4. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient must be available; and
5. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.
6. Patients with chronic intractable pain due to any of the following:
   - Lumbosacral adhesive arachnoiditis secondary to multiple myelographies or lumbar surgeries that has not responded to medical management, including physical therapy (the presence of arachnoiditis is usually documented by the presence of high levels of proteins in the CSF and/or by myelography or MRI.);
   - Nerve root injuries, post surgical or post traumatic (e.g., avulsion), including that of post-laminectomy syndrome (failed back syndrome);
   - Complex regional pain syndrome I & II (term causalgia reflex sympathetic dystrophy changed to complex regional pain syndrome I & II);
   - Phantom limb syndrome that has not responded to medical management;
   - Post-herpetic neuralgia;
   - Plexopathy;
   - Polyneuropathy
   - Intercostal neuralgia that did not respond to medical management and nerve blocks;
   - Cauda equina injury / syndrome;
   - Incomplete spinal cord injury
   - End stage peripheral vascular disease under the following circumstances:
     a. When the patient cannot undergo revascularization; or
     b. When revascularization has failed to relieve painful symptoms and the pain has not responded to medical management
• The management of intractable angina in patients who are not surgical candidates and whose pain is unresponsive to all standard therapies when all of the following criteria are met:

  a. Patient has documented significant coronary artery disease by angiography and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA), and

  b. Patient's angina pectoris is New York Heart Association (NYHA) Functional Class III (patients are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain) or Class IV (symptoms of cardiac insufficiency or angina are present at rest; symptoms are increased with physical activity), and

  c. Reversible ischemia is documented by symptom-limited treadmill exercise test, and

  d. Patient has had optimal pharmacotherapy for at least one month. Optimal pharmacotherapy includes the maximal tolerated dosages of at least two of the following anti-anginal medications: long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists; and

  e. Patient experiences significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation.

  **Note:** Criteria for exclusion from coverage of DCS in treating intractable angina pectoris include any of the following:

  a. Myocardial infarction or unstable angina in the previous 3 months, or

  b. Significant valve abnormalities as demonstrated by echocardiography, or

  c. Somatic disorders of the spine leading to insurmountable technical problems in treatment with DCS

**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 set that will not be accepted for billing or payment purposes until the October 1, 2015 implementation date.

**ICD-9 Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>053.19</td>
<td>Post herpetic neuralgia</td>
</tr>
<tr>
<td>322.2</td>
<td>Chronic arachnoiditis</td>
</tr>
<tr>
<td>337.21</td>
<td>Reflex sympathetic dystrophy of the upper limb</td>
</tr>
<tr>
<td>337.22</td>
<td>Reflex sympathetic dystrophy of the lower limb</td>
</tr>
<tr>
<td>337.29</td>
<td>Reflex sympathetic dystrophy of other specified site</td>
</tr>
<tr>
<td>353.0</td>
<td>Brachial plexus lesions</td>
</tr>
</tbody>
</table>
353.1 Lumbosacral plexus lesions
353.6 Phantom limb (syndrome)
353.8 Intercostal neuralgia
354.4 Causalgia of upper limb
354.8 Other mononeuritis of upper limb
354.9 Mononeuritis of upper limb, unspecified
355.71 Causalgia of lower limb
355.79 Other mononeuritis of lower limb
355.8 Mononeuritis of lower limb, unspecified
411.1 Intractable Angina
440.22 Atherosclerosis of extremities with rest pain
443.9 Peripheral vascular disease, unspecified (due to peripheral ischemic pain)
722.81 Postlaminectomy syndrome, cervical region
722.82 Postlaminectomy syndrome, thoracic region
722.83 Postlaminectomy syndrome, lumbar region
723.4 Brachial neuritis or radiculitis NOS
724.3 Sciatica—Neuralgia or neuritis of sciatic nerve
724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified—radicular syndrome of lower limbs
729.2 Neuralgia, neuritis, and radiculitis, unspecified
952.4 Cauda equina injury
953.0 Injury to cervical nerve root
953.1 Injury to dorsal nerve root
953.2 Injury to lumbar nerve root
953.3 Injury to sacral nerve root
997.60 Post amputation stump pain

**ICD-10 Codes**
B02.29 Other postherpetic nervous system involvement
G03.1 Chronic meningitis
G54.0-G54.9 Nerve root and plexus disorders
G56.4-G56.42 Causalgia of upper limb
G56.8-G56.92 Other specified mononeuropathies of unspecified upper limb
G57.70-G57.72 Causalgia of lower limb
G57.80-G57.9 Other specified mononeuropathies of lower limb
G90.5-G90.9 Complex regional pain syndrome I (CRPSI)
I20.0 Unstable angina
I70.22-I70.229 Atherosclerosis of native arteries of extremities with rest pain
I73.9 Peripheral vascular disease, unspecified
M54.10 Radiculopathy, site unspecified
M54.12 Radiculopathy, cervical region
M54.13 Radiculopathy, cervicothoracic region
M54.14 Radiculopathy, thoracic region
M54.15 Radiculopathy, thoracolumbar region
M54.16 Radiculopathy, lumbar region
M54.17 Radiculopathy, lumbosacral region
M54.30-M54.32 Sciatica
M79.2 Neuralgia and neuritis, unspecified
M96.1 Postlaminectomy syndrome, not elsewhere classified
S34.3 Injury of cauda equine
S14.2 Injury of nerve root of cervical spine
S24.2 Injury of nerve root of thoracic spine
S34.21 Injury of nerve root of lumbar spine
S34.22 Injury of nerve root of sacral spine
T87.9 Unspecified complications of amputation stump

**CPT Codes**

63650 Percutaneous implantation of neurostimulator electrode array, epidural
63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685 Incision and subcutaneous placement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex neurostimulator pulse generator, without reprogramming
95971 Simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972 Electronic analysis of complex spinal cord or peripheral (i.e, peripheral nerve, sacral nerve, neuromuscular) except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative subsequent programming. (Revised in 2016)
95973 Electronic analysis of complex spinal cord or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative subsequent programming, each additional 30 minutes after first hour (Code deleted in 2016)

**HCPCS Codes**

N/A

**Scientific Rationale – Update January 2016**

Tsigaridas et al. (2015) completed a systematic review in which nine RCTs were included that were categorized into two groups: RCTs comparing spinal cord stimulation (SCS) either with optimal medical treatment or inactive mode or low stimulation SCS; and those comparing SCS with alternative therapeutic interventions. Follow-up was short-term (1-6 months) in most studies, showing no major complications. Two studies reported a neutral effect regarding mortality. Regarding efficacy, most RCTs were in favour of SCS mainly in the short term. The most recent, multi-centre RCT reported no significant difference compared to the control group. RCTs investigating the efficacy of SCS were small and they demonstrated a small effect in angina improvement. Due to great differences in their design the interpretation of the results is complex. Before this method is recommended as a routine therapy for refractory angina, a larger, well-designed, multicentre RCT is needed.

**Scientific Rationale – Update January 2015**

Stangen et al (2014) performed a multicenter randomized clinical trial in 36 painful diabetic peripheral neuropathy (PDPN) patients with severe lower limb pain not responding to conventional therapy. Twenty-two patients were randomly assigned to
spinal cord stimulation (SCS) in combination with the best medical treatment (BMT) (SCS group) and 14 to BMT only (BMT group). The SCS system was implanted only if trial stimulation was successful. Treatment success was defined as ≥50% pain relief during daytime or nighttime or "(very) much improved" for pain and sleep on the patient global impression of change (PGIC) scale at 6 months. Trial stimulation was successful in 77% of the SCS patients. Treatment success was observed in 59% of the SCS and in 7% of the BMT patients (P < 0.01). Pain relief during daytime and during nighttime was reported by 41 and 36% in the SCS group and 0 and 7% in the BMT group, respectively (P < 0.05). Pain and sleep were "(very) much improved" in 55 and 36% in the SCS group, whereas no changes were seen in the BMT group, respectively (P < 0.001 and P < 0.05). One SCS patient died because of a subdural hematoma. The authors concluded treatment success was shown in 59% of patients with PDPN who were treated with SCS over a 6-month period, although this treatment is not without risks.

Liem et al (2014) reported that previous work has demonstrated the effectiveness spinal cord stimulation of the dorsal root ganglion (DRG-SCS) for pain associated with failed back surgery syndrome, complex regional pain syndrome, chronic postsurgical pain, and other etiologies through 6 months of treatment; The authors reported the maintenance of pain relief, improvement in mood, and quality of life through 12 months. Subjects with intractable pain in the back and/or lower limbs were implanted with an active neurostimulator device. Up to four percutaneous leads were placed epidurally near DRGs. Subjects were tracked prospectively for 12 months. Overall, pain was reduced by 56% at 12 months post-implantation, and 60% of subjects reported greater than 50% improvement in their pain. Pain localized to the back, legs, and feet was reduced by 42%, 62%, and 80%, respectively. Measures of quality of life and mood were also improved over the course of the study, and subjects reported high levels of satisfaction. Importantly, excellent pain-paresthesia overlap was reported, remaining stable through 12 months. The authors concluded despite methodological differences in the literature, DRG-SCS appears to be comparable to traditional SCS in terms of pain relief and associated benefits in mood and quality of life. Its benefits may include the ability to achieve precise pain-paresthesia concordance, including in regions that are typically difficult to target with SCS, and to consistently maintain that coverage over time.

Pak et al (2014) compared psychological and pain-related characteristics of patients with chronic pain and patients with refractory angina pectoris who had been treated with spinal cord stimulation (SCS) therapy. Twenty-four patients receiving SCS therapy were interviewed. Four psychological variables were assessed using standardized questionnaires for pain catastrophizing, health locus of control, anxiety sensitivity, and self-efficacy. Patients also completed the revised version of the Short-Form McGill Pain Questionnaire, the Short-Form Health Survey, and self-reported measures of global perceived effect, pain, functionality, and satisfaction with SCS therapy. Most patients reported improvements in pain, functionality, and improvement overall. Some health locus of control dimensions were significantly higher for the angina group than the chronic pain group, and chronic angina patients reported significantly lower levels of intermittent pain. Virtually all patients reported being satisfied with SCS therapy. The authors concluded most self-rated psychological and pain-related characteristics were no different between the two groups, which gives some support to the view that refractory angina is a form of chronic pain. The results also add to evidence supporting the use of SCS therapy for refractory angina pectoris; however, differences observed on a few variables may indicate points of focus for the assessment and treatment of such patients.
Scientific Rationale

The dorsal column stimulator (DCS), or spinal column stimulator (SCS), is a device that allows for electrical stimulation of the dorsal aspect of the spinal cord nerves in an effort to relieve pain in patients with a variety of chronic pain disorders. In most cases, neuropathic pain responds poorly to standard pharmacological and surgical therapies and can last indefinitely with increasing severity over time, and often results in severe disability. Stimulation in this area interferes with the conduction of pain impulses through adjacent sensory pathways and may stimulate endorphins. The technique does not alter the underlying pathological process. However, in selective patients with persistent and intractable pain of nerve origin, approximately 50 percent of patients will have pain relief, thereby decreasing the need for analgesic medication and at times obviating the need for further surgical procedures.

One or more epidural electrodes are inserted into the spinal canal over the dorsal aspect of the spinal cord. The locus of the electrode placement - cervical, thoracic, or lumbar - depends on the location of the patient's pain. The electrode is usually placed by a percutaneous technique, but on occasion (usually in a post-surgical patient), surgical placement (laminotomy) is required. The procedure is done in two stages. In the trial stage, the stimulating electrodes are usually inserted percutaneously via an epidural needle under fluoroscopic guidance and positioned to obtain optimal paresthetic coverage of the nociceptive areas. The wire is located outside of the body. After placement of the electrodes, the patient is provided with an external neurostimulator, initially on a trial basis, usually lasting from three to seven days. During the trial period, if it is determined that the modality is not effective or it is not acceptable to the patient, the electrodes are removed. If the trial has been successful, an adjustable, battery-operated spinal neurostimulator pulse generator or receiver is inserted subcutaneously and connected to the implanted electrodes already in place. A recent study concluded that electrodes placed via a thoracic laminectomy were associated with significantly better long-term effectiveness than electrodes placed percutaneously in patients with chronic pain involving the lower back and lower extremities which was refractory to conservative therapy.

The procedures are generally safe, but on occasion, complications may occur. The main complications associated with DCS relate to infection (e.g., wound infection, epidural abscess), bleeding, equipment failure (e.g., electrode migration, lead fractures, circuit leaks, battery failure, fibrosis of the stimulating tip), and the development of tolerance.

DCS is currently used to treat a wide variety of inoperable and intractable chronic pain syndromes. In patients with failed conservative and surgical treatment of lower-limb ischemia, DCS increases skin blood flow, decreases pain, and improves "quality of life." Four studies used inferential statistics and found pain reduction to be significant. At least 50% pain reduction at follow-up was found in 78%, 80%, and 85% of patients in the three studies that reported this data. Follow-up ranged from 6 to 35 months.

According to recent systematic reviews, the most favorable results have been observed in patients with peripheral vascular disease, complex regional pain syndrome, and peripheral neuropathy (e.g., diabetic or causalgic origin). Of interest, the pain relief achieved with DCS in patients with complex regional pain syndrome is possible without vasodilation. The vasodilation found with DCS is attributed to an
inhibitory effect on sympathetically maintained vasoconstriction. Diabetic patients with peripheral arterial occlusive disease who present with intractable pain have also been successfully treated with DCS, except those who have severe autonomic neuropathy. Recently, DCS has been successfully used to treat intractable angina pectoris and chronic mesenteric ischemia.

Six studies evaluated DCS for neurologic pain. Five studies used pain relief as the primary outcome measure, and one used the frequency of crossover to alternative treatment. In the only study using inferential statistics, all measurements of pain were significantly decreased. In the four studies measuring frequency and magnitude of pain reduction pain was reduced by at least 50% at follow-up in 47% to 62% of subjects. Follow-up ranged from 6 months to 15 years.

Spinal cord stimulation is proposed as a late or last resort treatment for chronic pain due to stable angina pectoris. Although most of the research reviewed used subjective outcome measures and some studies lacked prospective design, adequate sample size, and control groups, DCS was shown to alleviate pain and reduce myocardial ischemia in many of the study patients for whom pain relief was previously unobtainable. DCS has also been shown to reduce service utilization in aggregate among recipients. Side effects, while not infrequent, are rarely serious and can usually be resolved by the realignment or replacement of the device. Evidence indicates that the analgesic effect of DCS in angina does not mask the warning pain of myocardial infarction, and patients who have been treated with DCS have not been shown to be at increased risk for morbidity or mortality compared with their peers. Although a minority of patients receiving a trial of DCS ultimately experience prolonged pain relief, the significance of the alleviation of pain and suffering among those who do cannot be underestimated. Therefore, spinal cord stimulation for chronic stable angina pectoris secondary to demonstrable myocardial ischemia in patients who are refractory to treatment should be considered.

References – Update January 2016

References – Update January 2015

References – Update January 2014

References – Update January 2013
References – Update January 2012
2. McDonald JD, Fisher KJ. Technique for steering spinal cord stimulator electrode. Neurosurgery. 2011 Sep;69 (1 Suppl Operative)

References – Update April 2011

References – Update April 2008

References – Initial


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.