

# Clinical Policy: Spinal Cord Stimulation, Peripheral Nerve and Percutaneous Electrical Nerve Stimulation

Reference Number: NC.CP.MP.117

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[Coding Implications](#)

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See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

## Description

Peripheral nerve stimulation (PNS) is intended to decrease chronic and acute pain by stimulating peripheral nerves with leads placed adjacent or parallel to the affected nerve.<sup>18</sup> PNS can be used in a trial of pain relief effectiveness, or for permanent placement. In peripheral nerve field stimulation (PNFS), leads are placed in the region in which the pain is felt, stimulating smaller peripheral nerves and nerve endings.<sup>18</sup> PNFS is useful when one nerve does not clearly service the painful area.

Percutaneous electrical nerve stimulation uses fine needles as electrodes, which are placed in the soft tissues or muscles at dermatomal levels consistent with pain or pathology local pathology. It is similar to transcutaneous electrical nerve stimulation but bypasses the local skin resistance and delivers electrical current closer to the affected tissues.

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. It may result 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.

*Note: For other types of peripheral nerve stimulation, please refer to:*

- CP.MP.40 Gastric Electrical Stimulation
- CP.MP.137 Fecal Incontinence Treatments
- CP.MP.133 Posterior Tibial Nerve Stimulation for Voiding Dysfunction
- CP.MP.12 Vagus Nerve Stimulation
- CP.MP.203 Diaphragmatic/Phrenic Nerve Stimulation

## Policy/Criteria

- I.** It is the policy of Carolina Complete Health that there is sufficient evidence to support the efficacy of peripheral nerve stimulation or peripheral nerve field stimulation for any indication.
- II.** It is the policy of Carolina Complete Health that percutaneous electrical nerve stimulation (PENS) is medically necessary when meeting all the following:

- A. Diagnosis of diabetic neuropathy or diagnosis of neuropathic pain;
- B. Failed to adequately respond to a trial of at least three conventional treatments, unless contraindicated, and any of the following:
  - 1. Anticonvulsants (e.g., pregabalin);
  - 2. Antidepressants (e.g., amitriptyline, and duloxetine);
  - 3. Opioids (e.g., morphine sulphate and tramadol);
  - 4. Other pharmacological agents (e.g., capsaicin and isosorbide dinitrate spray);
- C. Request is for up to four weeks of PENS.
- D. PENS is not being used to treat lower back pain

**III.** It is the policy of Carolina Complete Health that spinal cord stimulation (SCS) is medically necessary for the following indications:

- A. *A trial of SCS for failed back surgery syndrome* when all the following criteria are met:
  - 1. Prior lumbar surgery;
  - 2. Neuropathic pain lasting  $\geq 6$  months, is refractory and interferes with activities of daily living (ADLs);
  - 3. Not a suitable candidate for or opposes additional surgery; Not a suitable candidate for or opposes additional surgery
  - 4. Failure of  $\geq 6$  months of conventional multidisciplinary medical therapy including all of the following:
    - a. Chiropractic, physical therapy or prescribed home exercise program;
    - b. NSAIDs (non-steroidal anti-inflammatory drugs) unless contraindicated or not tolerated;
    - c. Activity modification;
  - 5. Has demonstrated cognitive ability to manage stimulator;
  - 6. No inadequately treated major psychiatric disorders;
  - 7. Willingness to cease any inappropriate drug use prior to implantation.
- B. *A trial of SCS for complex regional pain syndrome (CRPS)* when all the following criteria are met:
  - 1. Pain is being managed by a pain management specialist with experience treating CRPS and pain/burning has persisted for  $> 6$  months;
  - 2. Has  $\geq 2$  of the following symptoms limited to one extremity only:
    - a. Allodynia (pain sensation in response to a typically non-painful stimulus) or hyperalgesia;
    - b. Swelling/tenderness;
    - c. Cyanotic/red/pale digit/extremity;
    - d. Increased sweating;
    - e. Alteration of temperature;
    - f. Persistent loss of motion;
    - g. Trophic skin changes;
    - h. Flexion contractures;
  - 3. Pain is chronic, refractory, and interferes with ADLs;
  - 4. Failure of  $\geq 6$  months of conventional multidisciplinary therapy including all of the following:
    - a. Physical therapy or occupational therapy;

- b. Anticonvulsant or antidepressant medication;
  - c. Sympathetic block;
  5. Has demonstrated cognitive ability to manage stimulator;
  6. No inadequately treated major psychiatric disorders;
  7. Willingness to cease any inappropriate drug use prior to implantation.
- C. *A trial of SCS for chronic ischemic leg pain due to peripheral vascular disease* when all of the following criteria are met:
1. Chronic, ischemic leg pain due to peripheral vascular disease and one of the following:
    - a. Not a candidate for revascularization;
    - b. Revascularization has failed to relieve painful symptoms and the pain has not responded to medical management;
  2. Pain lasting  $\geq 6$  months, is refractory and interferes with ADLs;
  3. Has demonstrated cognitive ability to manage stimulator;
  4. No inadequately treated major psychiatric disorders;
  5. Willingness to cease any inappropriate drug use prior to implantation.
- D. *A trial of SCS for the following indications* has **limited evidence** to prove effectiveness of treatment and consideration will be made on a case by case basis. Medical necessity will be considered in members based on the following information:
1. Chronic, intractable pain due to one of the following:
    - a. 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 cerebro spinal fluid and/or by myelography or magnetic resonance imaging);
    - b. Nerve root injuries, post-surgical or post-traumatic (e.g., avulsion);
    - c. Phantom limb syndrome that has not responded to medical management;
    - d. Post-herpetic neuralgia;
    - e. Plexopathy;
    - f. Polyneuropathy;
    - g. Intercostal neuralgia that did not respond to medical management and nerve blocks;
    - h. Cauda equina injury/syndrome;
    - i. Incomplete spinal cord injury;
    - j. Diabetic peripheral neuropathy;
    - k. Failed Neck Surgery Syndrome (FNSS)
    - l. ; Chronic, intractable back pain and/or lumbar radiculopathy
  2. Pain lasting  $\geq 6$  months, is refractory and interferes with ADLs;
  3. Specific goals have been established between the provider and the member/enrollee that include increased function, ADLs, return to work, and/or quality of life
  4. Failure of  $\geq 6$  months of conventional multidisciplinary medical therapy, including any of the following:
    - a. Physical therapy and/or chiropractic care
    - b. Physician-directed home exercises;

- c. Oral medication including opioid or non-opioids
  - d. Life-style changes, including diet, smoking cessation, and/or daily exercise;
  5. Has demonstrated cognitive ability to manage stimulator;
  6. No inadequately treated major psychiatric disorders;
  7. Willingness to cease any inappropriate drug use prior to implantation.
- E. *A trial of SCS for refractory chronic stable angina pectoris* has **limited evidence** to prove effectiveness of treatment and consideration will be made on a case by case basis. It should be reserved only for carefully selected members, if any. Medical necessity will be considered in members based on the following information:
1. Continued angina after percutaneous coronary intervention or coronary artery bypass graft;
  2. Not a candidate for further revascularization;
  3. Angina is NYHA (New York Heart Association) III (less than ordinary physical activity causes symptoms) or IV (symptoms present at rest);
  4. Reversible ischemia documented at least by a symptom-limited treadmill exercise test;
  5. Has had optimal pharmacotherapy for at least one month that includes the maximal tolerated dose of at least 2 of the following:
    - a. Long-acting nitrates;
    - b. Beta-adrenergic blockers;
    - c. Calcium channel antagonists;
  6. Pain is chronic, refractory, and interferes with ADLs;
  7. Has demonstrated cognitive ability to manage stimulator;
  8. No inadequately treated major psychiatric disorders;
  9. Willingness to cease any inappropriate drug use prior to implantation.
- F. *Permanent placement of a SCS* is **medically necessary** following a trial of spinal cord stimulation for an indication listed above when all of the following criteria are met:
1. Disease specific criteria for spinal cord stimulation are met;
  2. Documented trial of at least 48 hours.;
  3. Documented pain reduction of > 50% from the trial associated with functional improvement;
  4. The same brand and model of the generator device used for the trial is used for permanent placement.

**IV.** It is the policy of health plans affiliated with Centene Corporation that there is insufficient evidence to support the efficacy of dorsal root ganglion (DRG) stimulation.

## **Background**

### *Peripheral nerve stimulation (PNS)*

Evidence supporting peripheral nerve stimulation (PNS) is limited. According to a systematic review by Xu et al., there is a lack of high-quality randomized control trials to recommend PNS for most pain management indications.<sup>19</sup> They cited wide variations in experimental design, research protocol, and heterogeneity of study population as limitations preventing a meta-

analysis.<sup>19</sup> Xu et al. stated that PNS had level I and Level II evidence supporting its efficacy for migraine/chronic headache.<sup>19</sup> However, the large multicenter randomized clinical trial (RCT) included in the systematic review, conducted by Dodick et al. studying the effect of PNS for migraine headache, also noted adverse events among 70% of the study sample, with 48% of the patients with adverse events requiring hospitalization or further surgical intervention to treat the complication.<sup>20</sup> An additional systematic literature review noted moderate to strong evidence for peripheral nerves stimulation, but surveyed the literature as a whole for an array of pain indications, noting that further research could help “further refine appropriate populations and pain diagnoses.”<sup>26</sup> Hayes notes that there is insufficient evidence to evaluate the efficacy of peripheral nerve stimulation for back pain, or chronic neck pain.<sup>18</sup>

#### *Peripheral nerve field stimulation (PNFS)*

Hayes notes two available RCTs addressing PNFS for chronic low back pain, stating they were of low quality due to inability to blind patients and/or researchers, low sample sizes, and short follow-up periods.<sup>27</sup> An additional RCT evaluated subcutaneous PNFS combined with spinal cord stimulation (SCS) for refractory low back pain, concluding that PNFS significantly decreased pain compared to SCS alone.<sup>28</sup> Study limitations included industry ties amongst investigators and small sample sizes.<sup>28</sup> There were too few high-quality studies to support the safety or efficacy of PNFS for other indications.

#### *Percutaneous electrical nerve stimulation (PENS)*

The American Academy of Neurology’s 2011 guideline on treatment of painful diabetic neuropathy gives a B-grade recommendation for PENS as a treatment modality. They note one class I trial comparing PENS to sham treatment, yielding a 42% reduction in pain according to the visual analog scale.<sup>22</sup> The National Institute for Clinical Health and Care Excellence (NICE) also recommends PENS for refractory neuropathic pain, noting evidence of short-term efficacy and no significant safety concerns. NICE guidelines cite evidence from two RCTs with 64 and 50 patients, respectively, demonstrating significant reduction in pain and favorable safety profiles.<sup>25</sup>

#### *Spinal cord stimulation*

Spinal cord stimulation (SCS) is currently used to treat a wide variety of inoperable and intractable chronic pain syndromes, including failed back surgery syndrome and CRPS. In patients with failed conservative and surgical treatment of lower-limb ischemia, SCS 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 SCS in patients with complex regional pain syndrome is possible without vasodilation. The vasodilation found with SCS 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 SCS, except those who have severe

autonomic neuropathy. Recently, SCS has been successfully used to treat intractable angina pectoris and chronic mesenteric ischemia.

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, SCS was shown to alleviate pain and reduce myocardial ischemia in many of the study patients for whom pain relief was previously unobtainable. SCS 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 SCS in angina does not mask the warning pain of myocardial infarction. Patients who have been treated with SCS 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 SCS 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.

Slangen et al., performed a multicenter randomized clinical trial in 36 painful diabetic peripheral neuropathy (PDPN) patients with severe lower limb pain not responding to conventional therapy.<sup>13</sup> 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. Two year outcomes of the same study reported clinically significant improvements in pain and sleep in 53% of patients. Additionally, a randomized controlled trial of 60 patients, conducted by de Vos and colleagues, found that pain due to PDPN was significantly reduced from baseline at 6 months, and quality of life was improved.

#### *Dorsal Root Ganglion (DRG) Stimulation*

Hayes notes that currently there is insufficient evidence to determine the effectiveness and safety of DRG stimulation for adults with CRPS. According to Hayes, there is limited evidence suggesting that DRG stimulation for CRPS may result in successful outcomes for pain, quality of life, and mood, but conclusions could not be made due to the limited quantity of evidence, individual study limitations such as small sample sizes, and limited follow up. Additional high quality comparative studies are recommended to evaluate the benefits and risks of DRG stimulation for CRPS.<sup>31</sup>

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2021, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| <b>CPT® Codes</b> | <b>Description</b>   |
|-------------------|--|
| 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  |
| 64999             | Unlisted procedure, nervous system   |
| 64555             | Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)   |
| 64575             | Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)   |
| 64585             | Revision or removal of peripheral neurostimulator electrode array  |
| 64590*            | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling  |
| 64595*            | Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver   |
| 95970             | Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming                                      |
| 95971             | Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional  |
| 95972             | Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional |

\*For gastric electrical stimulation, refer to CP.MP.40 Gastric Electrical Stimulation

| <b>HCPCS Codes</b> | <b>Description</b>                                     |
|--------------------|--|
| L8679              | Implantable neurostimulator, pulse generator, any type |
| L8680              | Implantable neurostimulator electrode, each            |

| <b>HCPCS Codes</b> | <b>Description</b>  |
|--------------------|---|
| L8681              | Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only |
| 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, nonchargeable, includes extension                          |
| L8687              | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension                             |
| L8688              | Implantable neurostimulator pulse generator, dual array, nonchargeable, includes extension                            |

| <b>Reviews, Revisions, and Approvals</b>   | <b>Revision Date</b> | <b>Approval Date</b> |
|--|----------------------|----------------------|
| Policy split from CP.MP.63 Pain Management Procedures. Added chronic lower limb ischemia indication in I. C per Cochrane review of effectiveness. I.D. Case by-case indications: Added indications in I.D. per American Association of Neurological Surgeons 2008 information on SCS, and 2010 American Society of Anesthesiologists guidelines; added diabetic neuropathy indication. Added requirement for reversible ischemia documented by treadmill exercise test, per inclusion criteria in study by de Jongste. Added ICD-10 codes for diabetic neuropathy. | 07/16                | 07/16                |
| Took out requirement for more than 1 failed back surgery or failed back surgery at more than 1 level in failed back surgery syndrome (FBSS) indication (I.A.), as this was not supported by literature. Specified that pain in FBSS should be neuropathic. Added hyperalgesia as a symptom of CRPS. Coding updated.  | 07/17                | 07/17                |
| References reviewed and updated.   | 05/18                | 05/18                |
| Added Failed Neck Surgery Syndrome to indications under limited evidence criteria (I.D.1.k). Reviewed by specialist.   | 9/18                 | 09/18                |
| References reviewed and updated. Codes updated   | 3/19                 | 04/19                |
| Annual review completed. References and codes reviewed and updated. Reviewed by specialist.  | 2/20                 | 03/20                |
| Policy criterion revised to change length of an adequate trial of stimulation from >3 days to at least 48 hours.   | 4/21                 |                      |
| Annual review. Added policy statement, background, and references regarding peripheral nerve stimulation and peripheral nerve field stimulation in I. Added criteria, background, and references regarding percutaneous electrical nerve stimulation (PENS). Updated procedure codes. Added “chronic back pain” to criteria I.D.1. Changed “Review Date” in header to  | 05/22                | 05/22                |



| Reviews, Revisions, and Approvals   | Revision Date | Approval Date |
|---|---------------|---------------|
| <p>“Revision Date” and “Date” in the revision log header to “Revision Date.”<br/>References reviewed and updated. Reviewed by specialist.</p>   |               |               |
| <p>Annual review. Criteria II.A. updated verbiage to include “diagnosis of” neuropathic pain. Added Criteria II.D. regarding PENS not being used to treat low back pain. Updated Criteria III.A.3. to state, “Not a suitable candidate for or opposes additional surgery.” Criteria III.D.1.j. added “peripheral.” Criteria III.D.1.i. updated to say “Chronic, intractable back pain and/or lumbar radiculopathy.” Added Criteria III.D.3. Criteria III.D.4. updated to include examples of conservative therapy. Criteria III.F.4. updated to include “...same brand and model...” Added criteria IV. Regarding insufficient evidence to support dorsal root ganglion (DRG) stimulation. Background updated to include information regarding DRG stimulation for complex regional pain syndrome. Removed ICD-10 codes. References reviewed and updated. Reviewed by internal specialists.</p> | 04/23         | 04/23         |

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### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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