Electrical Stimulation and Electromagnetic Therapy for Wound Healing

Policy Number: HS-125

Original Effective Date: 8/20/2009

Revised Date(s): 8/20/2010; 8/2/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

Chronic wounds, including venous ulcers, diabetic foot ulcers, and pressure sores, are a major public health problem in the United States; the total prevalence of these wounds has been estimated to range from 3 to 6 million. Difficult-to-heal wounds lead to high rates of morbidity and mortality, negative effects on quality of life, and high healthcare costs. While leg and foot ulcers have numerous causes, such as venous disease, arterial disease, mixed venous-arterial disease, diabetic neuropathy, trauma, immobility, and vasculitis, over 90% of chronic lesions are related to venous disease, arterial disease, and neuropathy. Chronic wounds require intervention to promote healing and to prevent infection, progression, and recurrence.

Regardless of the cause, ulcer treatment usually begins with conservative therapies such as pressure relief, sterile dressings, and topical antibiotics. Debridement to remove necrotic tissue may also be necessary. If conservative treatments fail to promote wound healing, surgical treatments such as sclerotherapy of the affected vein, skin flap reconstruction, or amputation of a digit or foot may be necessary. A less invasive approach to management of chronic wounds involves electrical stimulation. This technique typically involves application of one electrode to the skin near the wound and application of a second electrode to saline-moistened gauze placed over the wound. The saline provides a conductive medium that allows electric current to pass directly through the wound. Although electrical stimulation for wound healing may involve electrical potentials as high as 200 volts, the parameters of stimulation such as pulse length or frequency of alternating current are adjusted such that muscle contractions do not occur since contractions could cause pain or disrupt healing.

Centers for Medicare and Medicaid Services Statement

ES and electromagnetic therapy have been used or studied for many different applications, one of which is accelerating wound healing. ES for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy uses a pulsed magnetic field to induce current. CMS was asked to reconsider its national noncoverage determination for electromagnetic therapy. After thorough review, CMS determined that the results from the use of electromagnetic therapy for the treatment of wounds were similar to the results from the use of ES. Therefore, effective July 1, 2004, Medicare will cover electromagnetic therapy for the same settings and conditions for which ES is covered. This means Medicare will allow either one covered ES therapy or one covered electromagnetic therapy for the treatment of wounds.

FDA Regulations

Electrical stimulation for wound healing is performed with devices similar to those designed to stimulate muscle contractions or to provide transcutaneous electrical nerve stimulation (TENS). These stimulators are regulated by the FDA as Class II devices, and over 500 of these devices have been approved via the FDA 510(k) process.

American Physical Therapy Association (APTA) Statement

According to the APTA, there is evidence that some forms of electrical stimulation enhance circulation and facilitate wound healing. When the Medicare Coverage Advisory Committee (MCAC) of the Health Care Financing Administration (HCFA) concluded that there was insufficient evidence that electrical stimulation improved healing of chronic wounds, the APTA filed a lawsuit against HCFA and obtained a reversal in the decision concerning noncoverage of this procedure.
National Pressure Ulcer Advisory Panel (NPUAP)

At a meeting of the MCAC held in October 2000, a representative of the NPUAP presented evidence concerning the efficacy of electrical stimulation for treatment of non-healing wounds. In February 2001, the Executive Committee of the MCAC gave unanimous approval for this use of electrical stimulation.

POSITION STATEMENT

The use of electrical stimulation (ES) and electromagnetic therapy are considered medically necessary for the treatment of the following types of chronic non-healing wounds:

- Stage III or IV pressure ulcers; OR,
- Arterial ulcers; OR,
- Diabetic ulcers; OR,
- Venous stasis ulcers

The use of ES and electromagnetic therapy is considered medically necessary only after 30 days of standard wound care has failed (The 30 day period may begin when the wound is acute). Standard wound care includes:

- Optimization of nutritional status
- Debridement by any means to remove revitalized tissue
- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings
- Necessary treatment to resolve any infection that may be present
- Frequent repositioning (usually every two hours) of a member with pressure ulcers
- Offloading of pressure and good glucose control for diabetic ulcers
- Establishment of adequate circulation for arterial ulcers
- Use of compression system for members with venous ulcers

ES and electromagnetic therapy is considered NOT medically necessary in the following circumstances:

- As an initial treatment modality; OR,
- Measurable signs of healing have not been demonstrated within a 30-day period of treatment*
- Treatment is used in an unsupervised setting (home use) as this has not been found to be medically reasonable and necessary

*Measurable signs of improved healing include:

- A decrease in wound size (either surface area or volume)
- Decrease in amount of exudates
- Decrease in amount of necrotic tissue

NOTE: ES or electromagnetic therapy MUST BE discontinued when the wound demonstrates 100% epithelialized wound bed.

CODING

Covered CPT® Codes

97014  Application of a modality to one or more areas; electrical stimulation (unattended)
97032  Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
ICD-9-CM Procedure Codes - No applicable codes

Covered HCPCS Level II® Codes

G0281 Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

Covered ICD-9-CM Diagnosis Codes

250.70 - 250.73** Diabetes with peripheral circulatory disorders [non-healing infected deep ulcerations (reaching tendons or bone) of the lower extremity unresponsive to at least 1 month of meticulous wound care, including aggressive debridement, maximal antibiotic therapy, tight glycemic control, and appropriate treatment of arterial insufficiency, including revascularization if necessary]

250.80 - 250.83** Diabetes with other specified manifestations [non-healing infected deep ulcerations (reaching tendons or bone) of the lower extremity unresponsive to at least 1 month of meticulous wound care, including aggressive debridement, maximal antibiotic therapy, tight glycemic control, and appropriate treatment of arterial insufficiency, including revascularization if necessary]

440.20 - 440.9** Atherosclerosis of native arteries and bypass graft of extremities [non-healing infected deep ulcerations (reaching tendons or bone) of the lower extremity unresponsive to at least 1 month of meticulous wound care, including aggressive debridement, maximal antibiotic therapy, tight glycemic control, and appropriate treatment of arterial insufficiency, including revascularization if necessary]

447.8 Other specified disorders of arteries and arterioles
454.0 Varicose Stasis Ulcer with varicose veins of lower extremities
454.2 Varicose veins of lower extremities with ulcer and inflammation
459.11 Postphlebitic syndrome with ulcer
459.13 Postphlebitic syndrome with ulcer and inflammation
459.81** Venous Stasis Ulcer without varicose veins
707.23 Pressure Ulcer Stages III
707.24 Pressure Ulcer Stage IV

**Requires a code for the associated ulceration, i.e. 707.10 – 707.9


REFERENCES

Peer Reviewed

Government Agencies, Professional and Medical Organizations
2. Association for the Advancement of Wound Care (AAWC). Summary algorithm for venous ulcer care with annotations of available evidence. Malvern (PA): Association for the Advancement of Wound Care (AAWC); 2005.

**HISTORY AND REVISIONS**

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