Clinical Policy: Low-Frequency Ultrasound and Noncontact Normothermic Wound Therapy

Reference Number: CP.MP.139 Coding Implications
Date of Last Revision: 07/21 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Low-frequency ultrasound debridement is a noncontact debridement method that provides simultaneous cleansing and debridement of wounds. It is generally performed at a 5 mm - 15 mm distance from the wound surface. A device uses ultrasound technology to atomize saline, delivering a continuous mist to the treatment site. Multiple passes over the wound are made with the treatment head of the device for a predetermined treatment session. This can accelerate the wound healing process by removing the necrotic tissue, fibrosis, exudate, and bacteria with minimum bleeding and pain.

Noncontact normothermic wound therapy (NNWT) utilizes radiant heat to provide an optimal environment for wound healing by maintaining 100% relative humidity and warming to normothermia in the wound bed.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that current evidence does not support the use of low-frequency ultrasound wound therapy.

II. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of noncontact normothermic wound therapy (NNWT).

Background

The treatment of chronic and difficult to heal wounds presents many clinical challenges. To ensure proper healing, the wound bed needs to be well vascularized, free of devitalized tissue, clear of infection, and moist. Surgical debridement is the most appropriate choice for removing large areas of necrotic tissue and is indicated whenever there is any evidence of infection (cellulitis, sepsis). Surgical debridement is also indicated in the management of chronic non-healing wounds to remove infection, handle undermined wound edges, or obtain deep tissue for culture and pathology.[1]

Low-frequency Ultrasound Wound Therapy

Noncontact, low-frequency ultrasound debridement devices have been proposed as adjunctive treatment of a variety of wounds including, but not limited to, acute, traumatic, chronic, and dehisced wounds. Several devices have received FDA approval, including but not limited to, The Mist Therapy System (Alliqua Biomedical), Qoustic Wound Therapy System (Arobella Medical, LLC), SonicOne Ultrasonic Wound Debridement System (Misonix Inc.) and Sonoca TM 180/1 96 Wound Care System. Evidence for the use of these devices to treat wounds is limited and consist of studies that lack adequate sample sizes. Results at this time are inconclusive.

A Cochrane database review of randomized control trials (RCTs) comparing ultrasound with no ultrasound in wound care identified two trials evaluating low frequency ultrasound. The trials reported healing at different time points. Both trials reported no evidence of a difference in the proportion of ulcers healed with ultrasound compared with no ultrasound. Both trials were significantly underpowered. The reviewers concluded there is no evidence of a benefit associated with low frequency ultrasound.[2] Several other small randomized controlled trials that compared patients treated with non-contact low-frequency ultrasound therapy in addition to standard wound care reported that outcome measures favored non-contact low-frequency ultrasound therapy in addition to standard wound care over standard wound care alone. However, the differences were not statistically significant.[3,4] A small RCT of 35 patients who received MIST Therapy plus the standard of wound care (treatment group) compared to 35 patients who received the standard of wound care alone (control group) for 12 weeks or until fully healed reported that a significantly higher percentage of patients treated with the standard of care plus MIST Therapy achieved greater than 50% wound healing at 12 weeks than those treated with the standard of care alone (63% vs 29%).[5] Additional research with larger randomized trials is necessary in order to demonstrate that low frequency ultrasound is beneficial for health outcomes in patients with wounds.

National Institute of Health Care Excellence (NICE)
The National Institute of Health Care Excellence (NICE) concluded, "The MIST Therapy system shows potential to enhance the healing of chronic, "hard-to-heal," complex wounds, compared with standard methods of wound management. However, the amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient to support the case for routine adoption of the MIST Therapy system. Comparative research is recommended to reduce uncertainty about the outcomes of patients with chronic, "hard-to-heal," complex wounds treated by the MIST Therapy system compared with those treated by standard methods of wound care."[6] In June 2016, NICE reviewed the guidance again and decided not to update it, noting new relevant evidence has been published but it is inconclusive.

Society for Vascular Surgery and the American Venous Forum.
The Committee suggests against ultrasonic debridement over surgical debridement in the treatment of venous leg ulcers. (Grade 2, Level of Evidence C) [7]

Noncontact Normothermic Wound Therapy
Noncontact normothermic wound therapy (NNWT) devices utilize radiant heat to promote wound healing and reportedly promotes wound healing by warming a wound to a predetermined temperature. The rationale underlying NNWT is that high moisture levels and physiologic temperatures promote wound healing. Physiologic temperature increases blood flow to the affected tissue, thereby increasing oxygenation, which increases collagen deposition, scar formation, and antibacterial processes. It is intended for the management of partial- or full-thickness chronic wounds.[8,9,10]

A 2002 Centers for Medicare and Medicaid Services (CMS) Decision Memo found that overall there were no high quality studies reviewed and while many of the studies gave a report of beneficial effect from the NNWT, they had serious methodological weaknesses, inadequate controls, and a variety of biases. It was found that improved outcomes could easily disappear in a

properly controlled randomized trial and that NNWT was not proven to heal any wound type better than conventional wound treatment. Due to these findings, a National Coverage Determination (NCD) was issued stating there is insufficient scientific or clinical evidence to consider this device as reasonable and necessary for the treatment of wounds and it would not be covered by Medicare.[8,9]

A 2003 Hayes Health Technology Assessment stated that the benefits of noncontact normothermic wound therapy are unproven due to insufficient published evidence, poor-quality studies, sparse data and conflicting results.[10] The report was archived in 2008 and no new data has since been published.

Coding Implications

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CPT® Codes	Description
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care; per day

HCPCS Code	Description
E0231	Noncontact wound-warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover
E0232	Warming card for use with the noncontact wound-warming device and noncontact wound-warming wound cover

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	01/17	02/17
References reviewed and updated	01/18	01/18
References reviewed and updated	01/19	01/19
References reviewed and updated. Codes checked.	11/19	12/19
Renamed policy to Low Frequency Ultrasound Therapy and Noncontact Normothermic Wound Therapy for Wound Management. Added criteria and background for noncontact normothermic wound therapy from WellCare policy HS-216 Wound Care. References reviewed and updated. Replaced “members’ with “members/enrollees” in all instances.	08/20	09/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review. References reviewed and updated. Coding reviewed. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." "Experimental/investigational" verbiage replaced in policy statement with descriptive language.	07/21	07/21

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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.

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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.

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Note: For Medicaid members/enrollees, 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/enrollees, 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.