Clinical Policy: Low-Frequency Ultrasound Therapy for Wound Management

Reference Number: PA.CP.MP.139
Effective Date: 04/18
Last Review Date:10/19

Coding Implications
Revision Log

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.

Policy/Criteria
It is the policy of PA Health & Wellness that low-frequency ultrasound wound therapy is considered **investigational**. This treatment continues to be evaluated in clinical studies. However, current peer reviewed literature is inconclusive at this time.

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]

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.

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]

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.

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 2019, 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.

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

CLINICAL POLICY

Low Frequency Ultrasound Therapy for Wound Management

HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that do NOT Support Coverage Criteria

ICD-10-CM Code	Description
ALL	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	04/18	06/18
References reviewed and updated.	02/19	
Annual review, no changes.	10/19	

References

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