Medical Policy Reference Manual
Medical Policy

2.01.069 Non-Contact Low-Energy Ultrasound Wound Care Therapy

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Description

Chronic wounds are those which fail to heal in an orderly manner in a series of stages within a predictable amount of time; a wound is generally considered chronic if healing does not take place within three months. Chronic wound types include venous and stasis ulcers, diabetic foot ulcers, and pressure sores. Over 90% are related to venous or arterial disease or nerve damage. The incidence also appears to be increasing, owing to population aging and an increasing incidence of diabetes and obesity.

Conservative care for chronic wounds usually begins with measures such as sterile dressing changes, topical antibiotics, and in the case of pressure sores, pressure relief. Gentle debridement of devitalized tissue may also be required. If conservative measures fail, treatments such as sharper debridement or a flap of donor tissue may be used. Low-frequency or low-energy non-contact ultrasound (US) energy delivered by saline mist has been investigated as a treatment for chronic wounds. The US-saline mist combination reportedly removes slough, exudate, fibrin and bacteria and promotes angiogenesis and growth factor production. The patient typically undergoes 3 sessions a week for 12 weeks.

Policy

Non-contact ultrasound treatment for wounds is considered **experimental / investigational** as it does not meet TEC criteria #2-5.

Policy Guidelines

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

The MIST Therapy® system (Celleration, Inc.) first received marketing clearance from FDA in June of 2004, and subsequently in May of 2005. It is considered a Class II device. Other devices that have received 510(k) clearances where the MIST Therapy® system was identified as the predicate device include the AR1000 and AS1000 Ultrasonic Wound Therapy System (Arobella Medical, Inc.) and the Sonic One Ultrasonic Wound Care System (Misonix, Inc.). The latter devices are direct-contact designs, whereas the MIST Therapy® system is non-contact.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The best available evidence for non-contact US/saline mist wound therapy comes from two randomized, controlled trials (RCT) that evaluated the MIST Therapy® system for foot and leg ulcers related to diabetes or limb ischemia (Ennis et al, 2005; Kavros et al, 2008). The results of these studies provide some evidence that MIST Therapy®

decreases wound volume, increases the incidence of complete wound closure, and decreases the amount of wound exudates significantly more than standard treatment. Although these results are promising, significant flaws in study design, e.g. small sample size, heterogeneous study populations, and loss of patients limit the ability of the results to permit conclusions regarding health outcomes. The first Ennis study was a multicenter double blinded RCT randomizing patients (n=133) to real or sham MIST Therapy® as an adjunct to standard wound care. There was a large loss of the enrolled group (78 patients) leaving only 27 in the treatment group and 28 in the sham group. In the per protocol analysis there was a considerable higher percentage of treatment patients with complete wound closure. In the intent-to-treat analysis the therapy did not show any significant improvements in wound healing. Another possible confounder is the fact that the US was delivered at 4-6 inches from the wound rather than at 0.5 to 1.5 cm as per the manufacturer's instructions. The Kavros study randomized 70 patients with non-healing foot and leg ulcers to MIST Therapy® or standard wound care. The majority of the population had coronary artery disease or diabetes mellitus. At 12 weeks wound volume had decreased by >50% in 22 US patients and 10 control patients. Information regarding complete wound healing was not reported. The same authors conducted a retrospective comparative study of MIST Therapy® in addition to standard wound care versus standard care alone. Outcomes measures included complete healing, rate of healing, wound closure percentage and wound volume. The authors reported that improvements were better in the MIST Therapy® group over controls for venous wounds, but not for other wound types. The authors did not discuss the statistical significance of the findings.

Overall there are seven studies addressing the safety and efficacy of the MIST Therapy® system, providing limited and preliminary evidence that as an adjunct to standard wound care the treatment improves healing of chronic foot and leg ulcers. The quality of the evidence overall is low due to heterogeneity of populations, lack of controls in several studies, small sample sizes, differences in treatment protocols, lack of blinding of observers, and non-standardized assessment of outcomes.

3. The technology must improve the net health outcome:

There was no indication of device-related adverse events described in the studies. However, the quality of the available studies is low, and while promising, the evidence is insufficient to reliably determine that MIST Therapy® improves the net health outcomes.

4. The technology must be as effective as any established alternatives:

There are a number of methods of treating chronic non-healing wounds, including vacuum-assisted closure, skin substitutes such as Apligraf®, Unna boot, and growth factors. No direct comparison studies were found, so it is unknown whether MIST Therapy® is at least as effective as other alternative.

5. The improvement must be attainable outside the investigational settings:

The evidence has not established a net improvement in the investigational setting; therefore it is not known whether to expect an improvement outside the investigational setting.

Update 2015:

A search of the peer-reviewed literature was performed from October 2012 through November 2014. Findings in the recent literature do not change the conclusions on non-contact low-energy ultrasound wound care therapy. Therefore, the policy statement is unchanged.

Update 2017:

A search of the peer-reviewed literature was performed from December 2014 through January 2017. Findings in the recent literature do not change the conclusions on non-contact low-energy ultrasound wound care therapy. Therefore, the policy statement is unchanged.

Update 2019:

A search of the peer-reviewed literature was performed from February 2017 through March 2019. Findings in the recent literature do not change the conclusions on non-contact low-energy ultrasound wound care therapy. Therefore, the policy statement is unchanged.

Update 2021:

A search of the peer-reviewed literature was performed from April 2019 through March 2021. Findings in the recent literature do not change the conclusions on non-contact low-energy ultrasound wound care therapy. Therefore, the policy statement is unchanged.

Cross References to Related Policies and Procedures

2.01.060 Electromagnetic and Electrical Stimulation for the Care of Chronic Wounds

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own, and may or may not be in agreement with those of CareFirst.

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This policy statement relates only to the services or supplies described herein. Coverage will vary from contract to contract and by line of business and should be verified before applying the terms of the policy.