Medica Coverage Policy

Policy Name: Noncontact, Low-frequency Ultrasound Therapy for Healing of Chronic Wounds
Effective Date: 6/18/2018

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Noncontact, low-frequency ultrasound therapy for healing of chronic wounds is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description
Noncontact, low-frequency ultrasound is a technology intended to remove necrotic tissue from chronic wounds (debridement) and to stimulate closure of non-healing wounds. The treatment involves holding an ultrasonic handset one centimeter away from the wound, applying a saline solution to the handset and generating a saline mist that is designed to carry low levels of ultrasonic energy into the wound. The treatment is purported to promote healing of acute, traumatic, and chronic wounds by stimulating cellular activities that contribute to healing and cleaning the wound surface. The therapy is usually delivered on an out-patient basis in three sessions per week with three to twelve minutes of treatment per session, depending on wound size.

FDA Approval
The MIST Therapy® System and Ultramist® Ultrasound Healing Therapy (Alliqua Biomedical, Inc.) are regulated by the FDA as a Class II device and classified as an ultrasound wound cleaner. The device was initially approved on May 17, 2005 (K050129). The AS1000 Ultrasound Wound Therapy System (Arobella Medical, LLC Minnetonka, MN) received FDA approval on June 19, 2009 (K091038). Approvals also include the Sonoca-180/195 (Soring GmbH), and the SonicOne Plus Ultrasonic Wound Care System (Misonix, Inc.).

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.
Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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

Original Effective Date: 7/1/2009

Re-Review Date(s):
3/27/2012
4/15/2015
4/18/2018
2/20/2020 – administrative update; format

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