ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 4, 2014

Dr. Greg McKinney, MD MBA
Cahaba Government Benefit Administrators®, LLC
Comments for Draft LCDs
P.O. Box 13384
Birmingham, AL 35202-3384

Submitted Electronically to: J10LCDComment@cahabagba.com

Re: DL 35300: Ultrasound Therapy for Wound

Dear Dr. McKinney,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to Cahaba's draft LCD on Ultrasound Therapy for Wounds**.** The Alliance is a nonprofit multidisciplinary trade association of health care professional organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our clinical specialty societies and organizations not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

The Alliance is particularly concerned about this LCD as it appears that Cahaba makes inappropriate generalizations that impact the outcome of this policy. The proposed LCD cites research on therapeutic ultrasound, typically used for muscles and connective tissue by physical therapists, but applies it to non-contact low-frequency ultrasound (NCLFU) for wound healing (MIST™). This generalization is inappropriate and inaccurate. The effects of kilohertz ultrasound and megahertz ultrasound are quite different, with orthopedic ultrasound having a frequency up to 82.5 times greater than for NCLFU.

Ultrasound has many medical indications, though different parameters are used for different purposes. As the chart below demonstrates, ultrasound may be used with a range of frequencies and intensities, and each combination has different properties, used for different purposes.

Ultrasound use	**Frequency**	**Intensity**
Diagnostic imaging	2-20 MHz (varies by tissue or body region being imaged)	Varies, but commonly 720 mW/cm2
High intensity focused ultrasound (for cancer treatment)	0.5-8 MHz (varies by location)	100-10,000 W/cm2
Bone healing	1.5 MHz	30 mW/cm2
Therapeutic (orthopedic)	1.0-3.3 MHz	<1.5 W/cm2

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Ultrasonic wound debridement	22.5-35 kHz	Adjustable, range not disclosed
Wound healing (MIST™)	40 kHz	1.5 W/cm2

The two frequencies are very different, and have different effects on the tissues. As such, research on one type of frequency cannot be applied to the other. Cahaba cites the following papers to support their decision to not allow for coverage of NCLFU: The Lundeberg, Eriksson, and three Cullum papers. However, none of these papers assess the effectiveness of NCLFU. Rather, they assess, therapeutic, higher frequency ultrasound. The Gottrup paper cited does not discuss ultrasound, but instead discussed shockwave therapy, which is, in fact, infrasound, and studies on that technology cannot be generalized to low-frequency ultrasound.

While the Alliance agrees that the evidence does not support the use of megahertz ultrasound in wound healing, there is evidence to support the use of NCLFU in wound healing. One of the studies cited in this draft LCD, the NICE paper, concluded "*The Committee considered that the MIST Therapy system showed promise in the treatment of chronic wounds and its use was supported by expert opinion*." It is worth noting that this paper was published in 2011, basing its assessment on an evaluation paper completed in 2010, which included no study more recent than 2009 in its analysis. This analysis summarized its findings as "*The studies show that the MIST therapy system appears to have a beneficial effect on wound healing and debridement which contributes to wound healing*."

Finally, guidelines from the Wound Ostomy and Continence Nurses Society (WOCN)[2,3], updated in 2008 and 2012, support the use of NCLFU in neuropathic and arterial insufficiency ulcers (strength of evidence B) and in wounds with borderline blood flow and without limb-threatening sepsis (strength of evidence C). The joint National Pressure Ulcer Advisory Panel-European Pressure Ulcer Advisory Panel guidelines from 2009[4] recommend the use of NCLFU for recalcitrant stage III and IV pressure ulcers.

While the evidence may not be as strong as for other modalities, being a somewhat newer intervention, there is adequate evidence for leading professional societies to endorse NCLFU in their guidelines, for expert opinion to support it, and the NICE technology assessment Cahaba cites to conclude that its use is supported and it is not an experimental therapy.

The Alliance urges Cahaba to look at studies and assessments of the correct frequency as studies/assessments that examine a different technology should not be used to reach conclusions on NCLFU. Furthermore, the Alliance urges Cahaba to continue coverage of NCLFU. If coverage for this modality is denied, then patients who have not benefitted from other advanced interventions will not have access to this treatment to help treat their wounds.

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On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

1. Serena T, Lee SK, Lam K, Attar P, Meneses P, Ennis W. The impact of noncontact, nonthermal, low-frequency ultrasound on bacterial counts in experimental and chronic wounds. *Ostomy Wound Manage.* Jan 2009;55(1):22-30.

2. Wound Ostomy and Continence Nurses Society. Guideline for Management of Wounds in Patients with Lower-Extremity Neuropathic Disease. In: Crawford PE, Fields-Varnado M, eds. *WOCN Clinical Practice Guideline Series, #3*. Mount Laurel, NJ: WOCN Society; 2012:116.

3. Wound Ostomy and Continence Nurses Society. Guideline for Management of Wounds in Patients with Lower-Extremity Arterial Disease. In: Bonham PA, Flemister BG, eds. *WOCN Clinical Practice Guideline Series, #1*. Mount Laurel, NJ: WOCN Society; 2008.

4. EPUAP, NPUAP. Treatment of Pressure Ulcers: quick reference guide. Washington, DC: National Pressure Ulcer Advisory Panel; 2009.