2.01.79	Noncontact Ultrasound Treatment for Wounds		
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Section:	2.0 Medicine	**Page:**	Page 1 of 14

Policy Statement

I. Noncontact ultrasound treatment for wounds is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

The following category I CPT code is specific to this treatment:

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

Description

Low-frequency ultrasound in the kilohertz range may improve wound healing. Several noncontact low-frequency ultrasound (NLFU) devices have received regulatory approval for wound treatment.

Related Policies

- Electrostimulation and Electromagnetic Therapy for Treating Wounds
- Negative Pressure Wound Therapy in the Outpatient Setting

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2005, the MIST Therapy® device (Celleration) was cleared for marketing by the FDA through the 510(k) process "to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria."[2,] In February 2015, Celleration was acquired by Alliqua Biomedical (Langhorne, PA). In August 2020, Sanuwave acquired related UltraMIST System assets.

In 2007, the AR1000 Ultrasonic Wound Therapy System (Arobella Medical, Minnetonka, MN) was cleared for marketing by the FDA through the 510(k) process, listing the MIST Therapy® system and several other ultrasonic wound debridement and hydrosurgery systems as predicate devices. The AR1000 system probe uses "contact or noncontact techniques to achieve intended wound therapy

modalities to promote wound healing."[3,]Indications in the 510(k) summary are listed as "Selective and non-selective dissection and fragmentation of soft and or hard tissue" and "Surgical, excisional or sharp-edge wound debridement (acute and chronic wounds, bums) for the removal of nonviable tissue including but not limited to diseased tissue, necrotic tissue, slough and eschar, fibrin, tissue exudates, bacteria and other matter."[3,]This device is now known as the Qoustic Wound Therapy System™ (K131096).

Several other devices have been approved as being substantially equivalent to the earlier devices. FDA product code: NRB.

Rationale

Background

Ultrasound (US) delivers mechanical vibration above the upper threshold of human hearing (>20 kHz). US in the megahertz range (1-3 MHz) has been used to treat musculoskeletal disorders, often by physical therapists. Although the exact mechanism underlying its clinical effects is not known, therapeutic US has been shown to have a variety of effects at a cellular level, including angiogenesis, leukocyte adhesion, growth factor, collagen production, and increases in macrophage responsiveness, fibrinolysis, and nitric oxide levels. The therapeutic effects of US energy in the kilohertz range have also been examined. Although the precise effects are not known, the low-frequency US in this range may improve wound healing via the production, vibration, and movement of micron-sized bubbles in the coupling medium and tissue.

The mechanical energy from the US is typically transmitted to the tissue through a coupling gel. Several high-intensity US devices with contact probes are currently available for wound debridement. Low-intensity US devices have been developed that do not require coupling gel or other direct contact. The MIST Therapy System delivers a saline mist to the wound with low-frequency US (40 KHz). A second device, the Qoustic Wound Therapy System, also uses sterile saline to deliver US energy (35 KHz) for wound debridement and irrigation.

US is intended as an adjunct to standard wound care. Therefore, the evidence is needed that demonstrates US plus standard wound care provides superior wound closure outcomes compared with standard wound care alone.

The primary endpoints of interest for trials of wound closure are as follows, consistent with 2006 guidance from the U.S. Food and Drug Administration (FDA) for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds[1,]:

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Literature Review

This evidence review was created in December 2007 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through December 29, 2023.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

This literature review focuses on evidence evaluating whether the addition of noncontact low-frequency ultrasound (NLFU) improves wound healing compared with standard treatment alone. Observational studies may be considered if they provide additional information on adverse events or durability.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Noncontact Low-Frequency Ultrasound

Clinical Context and Therapy Purpose

The purpose of noncontact low-frequency ultrasound therapy in individuals who have any wound type (acute or nonhealing) is to improve wound healing.

The question addressed in this evidence review is: Does the use of noncontact low-frequency ultrasound therapy improve the net health outcome in individuals with any wound type (acute or nonhealing)?

The following PICO was used to select literature to inform this review.

Populations

The relevant population(s) of interest are individuals with any wound type (acute or nonhealing).

Interventions

The therapy being considered is noncontact low-frequency ultrasound therapy.

Comparators

The following therapies/tools/rules/practices are currently being used to make decisions about wound care: Standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Tricco et al (2015) published an overview of systematic reviews on treatments for complex wounds, which reviewed multiple therapies including ultrasound.[4,] The review by Voigt et al (2011) was included. Conclusions related to ultrasound therapy are summarized in Table 1.

Table 1. Overview and Summary Conclusions of Systematic Reviews

Disorder	Intervention	Outcomes	Type of Review	QOE	Conclusion
Venous ulcer	US	Time to healing/rate of healing	SR w/o MA	Low/moderate	No difference
Venous ulcer	HFUS, LFUS, US	Proportion of patients with healed wounds	SR with MA	High	No difference
Mixed arterial/ venous ulcer	US	Wound area/size reduction	SR with MA	Low/moderate	Effective
Diabetic ulcer	US	Ulcer healing	SR w/o MA	Low/moderate	No difference
Pressure ulcer	US	Wound area/size reduction, time to healing/rate of healing	SR w/o MA	Low/moderate	No difference
Pressure ulcer	US	Proportion of patients with healed wounds	SR with MA	High and low/moderate	No difference
Pressure ulcer	US	Proportion of patients with healed wounds	SR w/o MA	Low/moderate	Uncertain (conflicting evidence or indeterminate)

Adapted from Trico et al (2015).[4,]
HFUS: high-frequency ultrasound; LFUS: low-frequency ultrasound; MA: meta-analysis; QOE: quality of evidence; SR: systematic review; US: ultrasound; w/o: without.

Tables 2 and 3 summarize systematic reviews that compare results from NLFU with standard care. The Voigt et al (2011) systematic review only included RCTs; studies used contact or noncontact ultrasound for treating chronic lower-limb wounds.[5,] Five RCTs on NLFU were identified, 1 of which was unpublished. A pooled analysis of 2 sham-controlled trials found a significantly smaller proportion of nonhealed wounds at 3 months in the NLFU group than in the control group (relative risk, 0.74; 95% confidence interval, 0.58 to 0.95; p=0.02). The 2 NLFU studies were those by Ennis et al (2005), described in the following section,[6,] and by Peschen et al (1997),[7,] which delivered ultrasound therapy with a dated device during foot bathing. A systematic review by Chang et al (2017)[8,] included all study types; however, only 2 of the RCTs (Ennis et al [2005][6,] and Kavros et al [2007][9,]) were included. Chang et al (2017) did not include meta-analyses, and the narrative synthesis did not provide complete information on the range of comparative effects; therefore, it is not included in the tables below.

Table 2. Systematic Review Characteristics

Study (Year)	Dates	Studies	Participants	N (Range)	Design	Duration, mo
Voight et al (2011)[5,]	Up to Mar 2011	2	Patients with chronic lower-limb wounds	22-55	RCTs	2-3

RCT: randomized controlled trial.

Table 3. Systematic Review Results

Study (Year)	Time to Complete Wound Healing	% Nonhealed Wounds at 3 mo	Pain Outcomes	Safety Outcomes
Voight et al (2011)[5,]				
Total N	NR	77	NR	NR
Pooled effect (95% CI)		RR=0.74 (0.58 to 0.95), p=0.02		
I^2, %		0		

CI: confidence interval; NR: not reported; RR, relative risk.

Randomized Controlled Trials

One double-blind, multicenter, sham-controlled trial and a number of unblinded RCTs comparing NLFU with standard wound care alone have been performed. Trials including at least 25 patients are described in the Tables 4-7 and the following text. All RCTs used MIST therapy and, other than Beheshti et al (2014)[10,] and Olyaie et al (2013),[11,] which did not report funding sources, all were industry-funded. One study addressed diabetic foot ulcers. Four RCTs included patients with venous leg ulcers and another evaluated treatment of split-thickness graft donor sites. All studies except that on split-thickness graft donor sites included patients with nonhealing wounds; eligibility criteria included wounds that had not healed after at least 4 weeks. Standard care interventions varied, but generally consisted of wound cleaning, noncontact dressings, compression and, if deemed necessary by providers, debridement. In 2 studies (White et al [2016][12,], Gibbons et al [2015][13,]), authors mentioned following national guidelines for the standard of care intervention. Prather et al (2015)[14,] did not describe the standard care intervention and Beheshti et al (2014) reported only that compression was used.

Table 4. Summary of RCT Characteristics[a]

					Interventions	
Author (Year)	**Countries**	**Sites**	**Dates**	**Participants**	**Active**	**Comparator**
White et al (2016)[12,]	UK	1	Aug 2012-Nov 2013	Patients with venous leg ulcers (≥6 wk)	• n=17 • NLFU: 3´/wk for 8 wk (after 2-wk run-in) + SOC	• n=19 • SOC: >1 visit per week for 8 wk
Gibbons et al (2015)[13,]	US	22	Apr 2012-Mar 2014	Patients with venous leg ulcers (≥30 d)	• n=40 • NLFU: 3´/wk for 4 wk + SOC	• n=41 • SOC: 3´/wk for 4 wk
Prather et al (2015)[14,]	US	1	Feb 2012-Jul 2013	Patients with split-thickness graft donor sites	• n=16 • NLFU: 1´/wk for 5 consecutive days (after 2-wk run-in) + SOC	• n=15 • SOC: 1´/wk for 5 consecutive days (after 2-wk run-in)
Olyaie et al (2013)[11,]	Iran	1	Apr 2011-Apr 2012	Patients with venous leg ulcers (≥4 wk)	• n=30 • NLFU: 3´/wk for 3 mo or until healed + SOC • n=30 • HFU: 3´/wk for 3 mo or until healed + SOC	• n=30 • SOC: 3´/wk for 3 mo or until healed
Beheshti et al (2014)[10,]	Iran	1	Apr 2011-Aug 2012	Patients with venous leg ulcers (≥4 wk)	• n=30 • NLFU: 3´/wk until healed + SOC • n=30 • HFU: 3´/wk until healed + SOC	• n=30 • SOC: Compression therapy (visit frequency NR)

					Interventions	
Kavros et al (2007)[9,]	US	1	2004-2006	Patients with nonhealing foot, ankle, or leg wounds (≥8 wk)	• n=35 • NLFU: 3´/wk for 12 wk + SOC	• n=35 • SOC: daily visits
Ennis et al (2005)[6,]	US, Canada	26	NR	Patients with diabetic foot ulcers	• n=70 • NLFU: 3´/wk for 12 wk + SOC	• n=63 • SOC: 3´/wk for 12 wk

NLFU: noncontact low-frequency ultrasound; NR: not reported; RCT: randomized controlled trial; SOC: standard of care.
[a] Includes trials with ≥25 participants.

Table 5. Summary of RCT Results[a]

Study (Year)	Time to Complete Wound Healing	% With Complete Wound Healing	Change in Wound Size	Pain Outcomes	Adverse Events
		At 8 Wk	Mean % Change in Wound Area at 8 Wk	Mean Reduction in VAS Pain Score at 8 Wk	No. of Events
White et al (2016)[12,]					
N	NR	36	36	36	36
NLFU+SOC		3 (16%)	-46.6%	-14.35	24
SOC		1 (6%)	-39.2%	-5.27	36
TE (95% CI)		NR	Diff = -7.4 (-33.4 to 18.6); p=0.57	Diff = -9.08 (-19.23 to 1.06); p=0.08	NR
		At 7 Wk	Mean % Change In Wound Area at 4 Wk	Mean % Reduction in VAS Pain Score at 4 Wk	
Gibbons et al (2015)[13,]					
N	NR	81	81	81	NR
NLFU+SOC		11 (28%)	-61.6%	-80%	
SOC		6 (15%)	-45.0%	-20%	
TE (95% CI)		NR	Diff/CI NR; p=0.02	Diff/CI NR; p=0.01	
		At 14 Days		Mean VAS Pain Score at 3 Wk	
Prather et al (2015)[14,]					
N	NR	NR	NR	NR	NR
NLFU+SOC	12.1 d	92%		0.04	
SOC	21.3 d	64%		1.0	
TE (95% CI)	HR/CI NR; p=0.04	NR		NR	
			Mean Wound Size at 4 Mo	Pain on 0-20 Scale at 4 Mo	
Olyaie et al (2013)[11,]					
N	90	NR	90	90	NR
HFUS+SOC	6.86 mo		3.23 cm^2	3.96	
NLFU+SOC	6.65 mo		2.72 cm^2	3.26	
SOC	8.50 mo		4.28 cm^2	5.10	
TE (95% CI)	Diff/CI NR; between 3 groups p=0.001		Diff/CI NR; between 3 groups p=0.02	Diff/CI NR; between 3 groups p=0.02	
				Pain on 0-20 Scale at 4 Mo	
Beheshti et al (2014)[10,]					
N	90	NR	NR		NR
HFUS+SOC	6.10 mo			4.20	
NLFU+SOC	5.70 mo			4.20	
SOC	8.13 mo			6.56	

Study (Year)	Time to Complete Wound Healing	% With Complete Wound Healing	Change in Wound Size	Pain Outcomes	Adverse Events
TE (95% CI)	Diff/CI NR; p<0.001[b]			Diff/CI NR; p<0.001[b]	
			% With 50% Reduction in Wound Volume at 12 Wk		
Kavros et al (2007)[9,]					
N	NR	NR		NR	NR
NLFU+SOC			63%		
SOC			29%		
TE (95% CI)			Ratio/CI NR; p<0.001		
		At 10 Wk		No. With Pain During Treatment, Pain Scale Not Described	% of Patients With Event
Ennis et al (2005)[6,]					
N	55[c]	133	NR	133	133
NLFU+SOC	9.2 wk	26%		1	• Mild: 51% • Moderate: 41% • Severe: 7%
SOC	11.0 wk	22%		3	• Mild: 46% • Moderate: 39% • Severe: 15%
TE (95% CI)	HR NR; p<0.014	Ratio/CI NR; p=0.69			Ratios/CIs NR; p=0.27

CI: confidence interval; Diff: difference; HFUS: high-frequency ultrasound; HR: hazard ratio; NLFU: noncontact low-frequency ultrasound; NR: not reported; RCT: randomized controlled trial; SOC: standard of care; TE: treatment effect; VAS: visual analog scale.
[a] Includes trials with ≥25 participants.
[b] The comparison for this p-value is unclear.
[c] Per-protocol analysis.

Limitations in the body of evidence are summarized in Tables 6 and 7 and the following paragraphs. Ennis et al (2005) published findings of a double-blind, multicenter, sham-controlled trial of MIST therapy for recalcitrant diabetic foot ulcers in 133 patients.[6,] Patients were treated with active or sham MIST therapy 3 times per week, with debridement as needed and a weekly evaluation by an independent investigator. Twenty-four patients were lost to follow-up, and data from 54 patients were excluded from analysis due to protocol violations (5 centers inverted the treatment distances for the active and sham devices), leaving 55 (41%) patients for the per-protocol analysis. Investigators reported significant improvement in the active treatment group (11/27 [41%] patients) compared with the control group (4/28 [14%] patients) in the proportion of wounds healed (defined as complete epithelialization without drainage). However, intention-to-treat analysis showed no difference in wound healing between the active (n=70 [26%]) and control (n= 63 [22%]) groups. In addition to the 59% loss to follow-up, there was a difference in the ulcer area at baseline (1.7 cm^2vs 4.4 cm^2, respectively) and chronicity of wounds (35 weeks vs 67 weeks, respectively) that favored MIST therapy in the per-protocol groups. Due to the serious limitations of this trial, these results are considered inconclusive.

In the White et al (2016),[12,] Gibbons et al (2015),[13,] and Prather et al (2015)[14,] studies, patients, and providers were not blinded, but outcome assessment was blinded. The other studies did not mention blinding. All but 1 RCT reported improved (statistically significant) results for the primary outcome

with NLFU than with standard of care. However, these studies had methodologic limitations. Regarding outcome assessment, complete healing is considered the most clinically relevant outcome.[15,] Complete healing was reported in a subset of the studies, and most were not powered for this outcome or the outcome used to power the study was unclear. Only Prather et al (2015)[14,]and Ennis et al (2005)[6,] conducted blinded outcome assessments and reported complete healing. Another limitation of the body of evidence is that some of the standard care interventions involved different visit schedules than the NLFU intervention, and the effects of this differential in face-to-face contact could partially explain the difference in findings between intervention and control groups.

Table 6. Study Relevance Limitations in RCTs

Study	Population	Intervention	Comparator	Outcomes	Follow-Up
White et al (2016)[12,]		3. Follow-up schedule for SOC involved fewer visits than NLFU	3. Follow-up schedule for SOC involved fewer visits than NLFU		
Gibbons et al (2015)[13,]				3. Adverse events not reported	
Prather et al (2015)[14,]			1. Did not describe SOC	3. Adverse events not reported	
Olyaie et al (2013)[11,]				3. Adverse events not reported	
Beheshti et al (2014)[10,]			2. Only compression used3. Details about frequency of SOC administration not provided	3. Adverse events not reported	
Kavros et al (2007)[9,]		3. Follow-up more intensive in SOC	3. Follow-up more intensive in SOC	1. Complete wound healing not reported 3. Adverse events not reported	
Ennis et al (2005)[6,]	None noted	None noted	None noted	None noted	None noted

NLFU: noncontact low-frequency ultrasound; SOC: standard of care
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations in RCTs

Study	Allocation	Blinding	Selective Reporting	Follow-Up	Power	Statistical
White et al (2016)[12,]		1. Not blinded assignment 2. Not blinded assessment				
Gibbons et al (2015)[13,]		1. Not blinded assignment 2. Not blinded assessment				
Prather et al (2015)[14,]		1. Not blinded assignment				

Study	Allocation	Blinding	Selective Reporting	Follow-Up	Power	Statistical
Olyaie et al (2013)[11],		1. Not blinded assignment 2. Not blinded assessment	1. Registration not documented in publication		1. No power calculations	
Beheshti et al (2014)[10],		1. Not blinded assignment 2. Not blinded assessment	1. Registration not documented in publication		1. No power calculations	
Kavros et al (2007)[9],		1. Not blinded assignment 2. Not blinded assessment	1. Registration not documented in publication		1. No power calculations	
Ennis et al (2005)[6],				1, 5. High number of protocol deviations and exclusions	1. No power calculations	

RCT: randomized controlled trials.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Supplemental Information

The purpose of the remaining sections in Supplemental Information is to provide reference material regarding existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement and information may not necessarily be used in formulating the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Association for the Advancement of Wound Care

In 2010 , the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers.[16] Noncontact low-frequency ultrasound therapy was included as a potential second-line intervention if first-line treatments did not result in wound healing.

The AAWC guidelines on the treatment of venous ulcers, updated in 2015, stated that low-frequency ultrasound treatment requires additional evidence before it can be considered an appropriate treatment.[17,]

National Institute for Health and Care Excellence

In 2011, the National Institute for Health and Care Excellence published a medical technologies guidance on the MIST Therapy system for the promotion of wound healing.[18,] The assessment concluded that "the amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient, at the time of writing, to support the case for routine adoption of the MIST Therapy system in the NHS." This guidance was last reviewed in 2016 with no changes to the recommendations. NICE states that the guidance will be reviewed in the future if there is new evidence that is likely to change the recommendations.

Society for Vascular Surgery, American Venous Forum, American Podiatric Medical Association

In 2014, the Society for Vascular Surgery in collaboration with the American Venous Forum published joint guidelines on the management of venous leg ulcers.[19,] The guidelines recommended adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after 4 to 6 weeks of standard wound therapy (strength of recommendation: grade 1; quality of evidence: level B), but recommended against routine ultrasound therapy for venous leg ulcers (strength of recommendation: grade 2; quality of evidence: level B). This guideline is currently archived.

In 2016, the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association published joint guidelines on the management of diabetic foot ulcers.[20,] The guidelines recommended adjuvant therapy for diabetic foot ulcers that fail to demonstrate more than 50% wound area reduction after 4 weeks of standard wound therapy. The adjunctive wound therapy options listed in the guidelines included negative pressure therapy, biologics (platelet-derived growth factor, living cellular therapy, extracellular matrix products, amniotic membrane products), and hyperbaric oxygen therapy. Ultrasound therapy was not mentioned as a recommended adjuvant option.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in December 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/30/2015	BCBSA Medical Policy adoption
03/01/2016	Policy revision without position change
03/01/2017	Policy revision without position change
03/01/2018	Policy revision without position change
03/01/2019	Policy revision without position change
03/01/2020	Annual review. No change to policy statement. Literature review updated.
03/01/2021	Annual review. No change to policy statement. Literature review updated.
03/01/2022	Annual review. No change to policy statement. Literature review updated.
03/01/2023	Annual review. No change to policy statement. Literature review updated.
03/01/2024	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent

therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Noncontact Ultrasound Treatment for Wounds 2.01.79 **Policy Statement:** I. Noncontact ultrasound treatment for wounds is considered **investigational**.	**Noncontact Ultrasound Treatment for Wounds 2.01.79** **Policy Statement:** I. Noncontact ultrasound treatment for wounds is considered **investigational**.