MASSACHUSETTS

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Medical Policy

Noncontact Ultrasound Treatment for Wounds

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Policy Number: 657

BCBSA Reference Number: 2.01.79
NCD/LCD: N/A

Related Policies

- Electrostimulation and Electromagnetic Therapy for Treating Wounds, #655
- Negative Pressure Wound Therapy in the Outpatient Setting, #543
- Noncontact Radiant Heat Bandage for the Treatment of Wounds, #656

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Noncontact ultrasound treatment for wounds is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code 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

Description

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 for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds[1,:]

1.Incidence of complete wound closure.
2.Time to complete wound closure (reflecting accelerated wound closure).
3.Incidence of complete wound closure following surgical wound closure.
4.Pain control.

Summary

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.

For individuals who have any wound type (acute or nonhealing) who receive noncontact ultrasound therapy plus standard wound care, the evidence includes randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The single, double-blinded, sham-controlled randomized trial, which included patients with nonhealing diabetic foot ulcers, had substantial methodologic flaws (eg,

high dropout rate, baseline differences between groups) that limit the validity of the findings. In the remaining studies comprising the evidence base, all but one RCT comparing NLFU with standard wound care reported improved (statistically significant) results on the primary outcome with NLFU. However, these studies also had several methodologic limitations. Complete healing is the most clinically relevant outcome. None of the RCTs evaluating venous leg ulcers reported complete healing as its primary outcome measure, and none had blinded outcome assessment. Only one RCT, which addressed split-thickness graft donor sites, reported on the proportion of patients with complete healing and had blinded outcome assessment. Another limitation of the body of evidence is that some standard of care interventions involved fewer visits than the NLFU intervention, and the differences in intensity of care resulting from this differential in face-to-face contact could partially explain the difference in findings between intervention and control groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
3/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
3/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
2/2018	New references added from BCBSA National medical policy.
2/2017	New references added from BCBSA National medical policy.
12/2016	New references added from BCBSA National medical policy.
3/2016	New references added from BCBSA National medical policy.
12/2014	New references added from BCBSA National medical policy.
2/2014	New references added from BCBSA National medical policy.
1/2014	Updated to add new CPT code 97610 and remove deleted code 0183T.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/2011	BCBSA National medical policy review. Changes to policy statements.
11/2011	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
12/2010	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
12/2009	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
9/2009	BCBSA National medical policy review. No changes to policy statements.
6/2009	BCBSA National medical policy review. No changes to policy statements.
4/2009	BCBSA National medical policy review. No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
1/2009	BCBSA National medical policy review. No changes to policy statements.
12/2008	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
10/2008	BCBSA National medical policy review. No changes to policy statements.

7/2008	BCBSA National medical policy review. Changes to policy statements.
5/2008	BCBSA National medical policy review. Changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
2/2008	BCBSA National medical policy review. Changes to policy statements.
8/2007	BCBSA National medical policy review. No changes to policy statements.
3/2007	BCBSA National medical policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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2. Food and Drug Administration. MIST[TM] Therapy System: 510(k) Premarket Notification: K050129. https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf. Accessed November 1, 2019.
3. Food and Drug Administration. 510(k) Summary: 510(k) -AR1000 Series K131096, Arobella Medical, LLC. 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131096.pdf. Accessed November 1, 2019.
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