Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Extracorporeal Shock Wave Treatment of Wounds

Description/Background

Acute wounds normally heal in an orderly and timely manner with proper wound management. Healing can be impaired by vascular disease, infection, immunosuppression, unrelieved pressure, radiation injury, poor nutrition, diabetes or other metabolic disorders. Wounds that fail to heal normally can develop into chronic non-healing wounds that are difficult to manage. A variety of wound healing modalities have been proposed to treat chronic wounds.

Extracorporeal shock wave treatment (ESWT) has been proposed for use in the treatment of both acute and chronic wounds. ESWT uses shock waves to stimulate tissue regeneration. The specific mechanism of action is unknown. Preliminary studies indicate that ESWT may accelerate wound healing by promoting an inflammatory response resulting in neovascular proliferation that might improve wound healing.

Regulatory Status

On December 28, 2017, the U.S. Food and Drug Administration (FDA) approved the dermaPACE® System (SANUWAVE, Inc) for marketing. According to the FDA approval letter, dermaPACE is a prescription device, "indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The dermaPACE System is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care."[1]

Medical Policy Statement

Extracorporeal shock wave treatment of wounds is considered **experimental/investigational**. There is insufficient evidence in the peer-reviewed medical literature establishing the safety and efficacy of this treatment modality.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0512T 0513T

Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Snyder et al (2018) reported on 2 double-blind randomized sham-controlled trials evaluating ESWT (dermaPACE) for treatment of patients with diabetic foot ulcers (DFU)[2]. The goal of the trials was to investigate the efficacy of ESWT as an adjunctive treatment for neuropathic diabetic foot ulcers compare with sham treatment. Treatment groups were either standard care and focused ESWT (dermaPACE System) or standard care and sham therapy. Study 1: active and sham treatments were administered 4 times in 2 weeks. Study 2: active and sham treatments were administered a maximum of 8 times over 12 weeks. Standard care continued in both studies through a 12-week treatment phase. The two studies evaluated 336 patients, 172 in the treatment arm and 164 in the sham arm. Neither trial met the primary efficacy endpoint of complete wound closure at 12 weeks. Study results indicated improved healing at 20 weeks with the addition of dermaPACE ESWT versus standard treatment of DFU; however, additional studies are needed to confirm these findings. SANUWAVE provided funding, consultants and clinical support in both of these trials.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Published			
NCT00536744	Effectiveness of dermaPACE™ Device and Standard Treatment Compared to Standard Treatment Alone for Diabetic Foot Ulcers	206	June 2010
Unknown Status			
NCT01824407	A Comparison of the dermaPACE® (Pulsed Acoustic Cellular Expression) Device in Conjunction With Standard of Care Versus Standard of Care Alone in the Treatment of Diabetic Foot Ulcers		(last updated in 2014)

Government Regulations
National/Local:

There is no national or local coverage determination regarding extracorporeal shock wave treatment of wounds.

Wisconsin Physicians Service Insurance Corporation, Local Coverage Article: Billing and Coding: Category III Codes (A56902)
Original Effective Date 08/29/2019
Revision Effective Date 08/29/2024

CPT codes 0512T, 0513T are not listed as reasonable and necessary codes.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Extracorporeal Shock Wave Therapy for Treatment of Plantar Fasciitis and other Musculoskeletal Conditions
- Hyperbaric Oxygen Therapy, Systemic and Topical
- Non-Contact Ultrasound Treatment for Wounds
- Platelet Rich Plasma Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and other Non-Orthopedic conditions.
- Wound Therapy (BCN only)

References

1. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, approval letter for DEN160037 dermaPACE system, December 28, 2017. https://www.accessdata.fda.gov/cdrh_docs/pdf16/DEN160037.pdf (Accessed 9/20/24).
2. Snyder R, Galiano R, Mayer P, et al. “Diabetic foot ulcer treatment with focused shockwave therapy: two multicentre, prospective, controlled, double-blinded, randomised phase III clinical trials,” J Wound Care, 2018. Vol. 27, No. 12, pp.822-836.
3. Wisconsin Physicians Service Insurance Corporation, Local Coverage Article: Billing and Coding: Category III Codes (A56902). Revision Effective Date 08/29/2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 9/20/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/12	6/12/12	6/15/12	Joint policy established
3/1/14	12/10/13	1/6/14	Routine maintenance; updated references, rationale, and policy statement. Removed “lower extremity” from the policy title.
3/1/16	12/10/15	12/10/15	Routine maintenance
3/1/17	12/13/16	12/13/16	Routine maintenance
3/1/18	12/12/17	12/12/17	Routine maintenance Code update – deleted T codes; added unlisted procedure code
3/1/19	12/11/18		Routine maintenance Added FDA approval information; 0512T and 0513T added, effective 1/1/19
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance
3/1/23	12/20/22		Routine maintenance (jf) 0512T, 0513T nomenclature revised
3/1/24	12/19/23		Routine maintenance (jf) Vendor Managed: NA
3/1/25	12/17/24		Routine maintenance (jf) Vendor Managed: NA Added clinical trial table

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: EXTRACORPOREAL SHOCK WAVE TREATMENT OF WOUNDS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.