

Molina Clinical Policy

Extracorporeal Shock Wave Therapy in the Treatment of Chronic Diabetic Foot Ulcers: Policy No. 377

Last Approval: 08/14/2024

Next Review Due By: August 2025



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Diabetic Foot Ulcers (DFUs) affect over 10% of diabetic patients and are associated with significant morbidity, as it is the most common cause of lower extremity amputation. Treatment aim is ulcer healing to prevent secondary infection, recurrence, and amputation. All ulcers, regardless of stage and depth, require appropriate debridement, effective local wound care, mechanical offloading, and infection control. Chronic DFUs are characterized by nonhealing foot ulcers lasting more than 3 months in diabetic patients, and are classified as neuropathic, ischemic, or neuroischemic dependent on their etiology.

Extracorporeal shock wave therapy (ESWT) is a non-invasive treatment via a device that delivers focused low- or high-energy shock waves to a specified body location to facilitate wound healing. Pressure waves travel through fluid and soft tissue, affecting areas with a change in impedance, such as bone/soft-tissue interfaces. The therapy has been shown to reduce inflammation, promote neovascularization and cell proliferation, and accelerate epithelialization, hence boosting chronic diabetic ulcer healing rates (NICE 2009b, 2012c). Low dose/low energy shockwave therapy necessitates repeated treatments one week to one month apart and is typically painless. High dose/ high energy shockwave therapy is administered in a single treatment and requires some form of anesthetic.

Regulatory Status

The dermaPACE system (Sanuwave) was the first ESWT system FDA approved for the treatment of DFUs. It was approved in December 2017 via the De Novo clearance process under product code PZL. Since dermaPACE's approval several ESWT systems have been approved via the 510(k)-clearance system under the product code PZL. These systems include Orthogold (Tissue Regeneration Technologies LLC), Storz Medical Duolith (Storz Medical AG), and OW100s (Softwave). All these devices are approved to treat chronic full thickness DFUs with wound areas spanning up to 16 cm² that extend through the epidermis, dermis, tendon, or capsule, but do not include bone exposure. The devices are intended to treat adults with DFUs greater than 30 days in duration and is intended as an adjunctive therapy to standard DFU care.

COVERAGE POLICY

Extracorporeal shock wave therapy for diabetic foot ulcers is considered **experimental, investigational, or unproven** due to insufficient evidence in peer reviewed medical literature that have not established safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

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SUMMARY OF MEDICAL EVIDENCE

Vangaveti (2023) conducted a six-week single center randomized trial to assess wound healing in those treated with extracorporeal shock wave therapy (ESWT) in addition to standard wound care versus standard wound care alone, with a secondary objective of assessing inflammatory markers. Twenty-five patients were allocated to the ESWT + standard wound care group, and twenty-three to standard wound care alone group. Though it did not reach statistical significance, more patients had healed diabetic foot ulcers (DFUs) at week 6 in the ESWT + standard wound care group than those in the standard wound care alone group. Both groups had similar levels of circulating inflammatory markers. The authors concluded ESWT showed promise in healing DFUs and warranted further research. The limitations of this study were small sample size, short duration, and risk of performance and detection bias.

Hitchman et al. (2019) conducted a systematic review examining the efficacy of ESWT on healing of DFUs. The review comprised five trials including 255 patients, published between 2009 and 2016. ESWT was compared to standard wound care in 3 studies and to HBOT in 2 studies. The Cochrane Risk of Bias Tool determined that all studies had an unclear to high risk of bias. ESWT was superior to standard wound care at complete wound healing and time to healing (64.5 ± 8.06 days versus 81.17 ± 4.35 days). ESWT was more effective than HBOT in improving DFU healing. There was variable evidence of effect on the blood flow perfusion rate. Infection rate and amputation rate were not reported. According to the findings of this systematic review, ESWT has the potential to improve healing in DFUs, but there is insufficient evidence to recommend its use in routine clinical practice currently. Hitchman et al. (2023) then conducted an updated systematic review of the literature regarding ESWT therapy for DFUs. Six trials met the inclusion criteria with the main objective being wound healing time. Utilizing the Cochrane Risk of Bias 2 Tool and GRADE approach the trials were analyzed to reveal unclear or high risk of bias across all domains. Across the six trials a total of 471 participants were included and were found to have shorter healing time, being more likely to heal at 20 weeks post treatment, with ESWT in conjunction with standard wound care than those treated with standard wound care alone. ESWT remains a promising new treatment, however, due to the heterogeneity of treatment administration in trials it is difficult to translate this therapy into a standard clinical practice.

Huang et al. (2020) performed a systematic review and meta-analysis of 8 RCTs ($n = 339$) to assess the safety and efficacy of ESWT on the healing of DFUs. All the included studies were conducted by different medical centers in different countries with varied treatment protocols for treatment strength, frequency, and duration. Patient ages ranged from 56.2 to 67.8 years. The control groups in the studies also received various treatments with standard wound care in 6 RCTs and hyperbaric oxygen therapy in 2 studies. The authors concluded that ESWT was associated with better outcomes as evidence by a greater reduction of the wound surface area by 1.54 cm^2 , an increase of re-epithelialization by 26.31%, and more patients with complete cure at the end of treatment compared to other therapies. Among the limitations mentioned by the authors include the restriction of ESWT to DFUs wounds, the small number of studies included in the meta-analysis (<10), and the absence of a study of cost effectiveness.

Snyder et al. (2018) conducted two multicenter, prospective, controlled, double-blind, randomized phase 3 clinical trials to assess the efficacy of focused ESWT as an adjuvant treatment for neuropathic DFUs compared with sham treatment. The two studies analyzed 336 patients: 172 treated with active therapy and 164 with a sham device. Patients in Study 1 were 18 years old or older, whereas patients in Study 2 were 22 years old or older. Both studies included individuals who had at least one diabetic foot ulcer in the ankle area or lower for at least 30 days before the screening visit. Participants could have more than one diabetic foot ulcer, however this trial only treated one. Prior to randomization, eligible patients were enrolled in a two-week run-in period during which only conventional care was provided. Patients who had a wound volume reduction of more than 50% were not eligible for randomization to ensure that only patients whose wounds were unresponsive to standard care were randomized. Patients in both studies were randomly assigned to either standard care with focused ESWT active therapy (pulsed acoustic cellular expression, dermaPACE System, Sanuwave Health Inc.) ($n=172$, combined) or standard care with sham therapy ($n=164$, combined). Standard care includes sharp debridement according to local practice, sterile saline-moistened gauze, adherent or non-adherent secondary dressings including foams and hydrocolloids, and pressure-relieving footwear. Antibacterial products were not permitted. In trial one, both active and sham therapy were provided four times in two weeks, and a total of eight times over a 12-week period in study two. Both studies continued standard care throughout the 12-week therapy phase and followed patients for up to 24 weeks. Both trials assessed wound closure within 12 weeks. In Studies 1 and 2, and in the pooled analysis, the primary outcome was not met. However, the active treatment

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arm repaired statistically substantially more DFUs at 20 (35.5% vs. 24.4%) and 24 weeks (37.8% vs. 26.2%) than the sham-controlled arm. Both trials failed to achieve wound closure at 12 weeks (DERM01 and DERM02; Snyder et al., 2018). Insufficient evidence available to determine if ESWT with the dermaPACE system increases wound healing in DFUs patients.

National and Specialty Organizations

The **ECRI Institute** issued a Clinical Evidence Assessment on the dermaPACE System that compared the device to conventional treatment and other chronic wound therapies (ECRI 2020). When comparing dermaPACE to standard of care alone, ECRI determined that the evidence is relatively favorable since it appears to increase DFU healing rates at 24-week follow-up and decreases time to wound closure. ECRI's recommendation was based on two low-quality RCTs (n=206, n=130) that were multi-centered and double-blinded, using data from the same study participants. A third RCT from a single-center, open-label trial (n = 77; 84 ulcers) compared dermaPACE with HBOT in patients with chronic DFUs and reported rates of full wound closure, better healing, unchanged ulcers, and side effects.

The **International Working Group on Diabetic Foot** issued *Practical Guidelines on the Prevention and Management of Diabetes-related Foot Disease* which outlines recommendations on the treatment of DFUs based on the most current evidence. The guideline did not mention ESWT as a recommendation for non-healing DFUs (Schaper et al. 2023)

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound
0513T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

08/14/2024	Policy reviewed and updated. No changes to coverage criteria. IRO Reviewed by a practicing physician board certified in Podiatry/ Foot and Ankle Surgery on June 28, 2024.
08/09/2023	Policy reviewed and updated. No coverage criteria changes.
08/10/2022	Policy reviewed and updated. No coverage criteria changes.
08/11/2021	Policy reviewed. No changes in coverage criteria. Updated references.
08/10/2020	New Policy. IRO policy reviewed by practicing MD board-certified in Surgery General, Wound Care.

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