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

Last Approval: 8/09/2023
Next Review Due By: August 2024

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 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

The **dermaPACE system** is a targeted ESWT for the treatment of DFUs. The dermaPACE device employs a patented type of ESWT known as Pulsed Acoustic Cellular Expression (PACE) therapy. PACE, according to the manufacturer Sanuwave Health, uses high-energy acoustic pressure waves in the shock wave spectrum to induce compressive and tensile stresses on cells and tissue structures. PACE treatment promotes increased circulation, biofilm destruction, cytokine and chemokine effects, growth factor upregulation, and angiogenesis, all of which result in the regeneration of tissue such as skin, musculoskeletal, and vascular structures. The safety and efficacy of the dermaPACE System was evaluated in two double-blind, parallel group, sham-controlled, multicenter, 24-week pivotal clinical trials involving 336 patients [DERM01 and DERM02 (Snyder et al. 2018)].

The dermaPACE System was subjected to a de novo premarket review, which is a regulatory procedure for certain low- to moderate-risk devices of a new type for which no legally marketed predicate device may claim substantial equivalence. The FDA determined that the dermaPACE system should be classified as a Class II along with a basic comparable device of this generic type. The FDA classifies this device as an 'extracorporeal shock wave device for chronic wound treatment,' which is a prescription device that focuses acoustic shock waves onto dermal tissue. Shock waves are produced within the device and transmitted to the body via an acoustic interface. The dermaPACE System was FDA-approved on December 28, 2017.

The dermaPACE System is indicated for the delivery of acoustic pressure shock waves in the treatment of chronic, full-thickness DFUs with wound areas spanning up to 16 cm^2 that extend through the epidermis, dermis, tendon, or capsule, but do not include bone exposure. The dermaPACE System should be used in conjunction with routine diabetic ulcer therapy for patients over the age of 22 who present with DFUs lasting more than 30 days and treatment with dermaPACE is generally provided in a physician’s office or outpatient in 4 to 8 brief, non-invasive applications over 2 to 10 weeks. Observation and routine care are required after treatment.

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.

SUMMARY OF MEDICAL EVIDENCE

Studies and Clinical Trials

Vangaveti (2023) conducted a six-week single center randomized trial to assess wound healing in those treated with 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 DUFs at week 6 in the EWST + 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.

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 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.

Wang et al. (2014) published the findings of a cohort study in which 67 patients (n=72 ulcers) received ESWT for chronic foot ulcers. In the diabetic mellitus (DM) group, there were 38 patients (n=40 ulcers) and in the non-diabetes mellitus (non-DM) group, there were 29 patients (n=32 ulcers). Patients with recurrent or persistent non-healing diabetic or nondiabetic ulcers of the foot for > 3 months were included in the study. All patients underwent ESWT in

the afflicted foot 6 times per week for 3 weeks utilizing the dermaPACE device (Sanuwave, Alpharetta, GA). The outcomes assessed chronic foot ulcer healing by clinical assessment and tissue viability determined by local blood flow perfusion scans preoperatively and postoperatively at 6 weeks, 1 year, and 5 years. Mortality and morbidity were two other outcome measures. Ten patients (n=9 in the DM group, n=1 in the non-DM group) were lost to follow-up. At 3-month, 1 year, and 5 years, the non-DM group's clinical results were considerably better than those of the DM group. Both the DM and non-DM groups improved their blood flow perfusion rates significantly. In both the DM and non-DM groups, blood flow perfusion rates improved significantly. Following ESWT, the improvements in blood flow perfusion rate began at 3 weeks and lasted up to 1 year. From 1 to 5 years, however, the blood flow perfusion rate in both groups dropped. At 5 years, the non-DM group had considerably superior blood flow perfusion compared to the DM group. From 1 to 5 years following treatment, the overall mortality rate was 15%, 24% in the DM group, and 3% in the non-DM group. Amputation occurred at a rate of 11% in the whole series, 17% in the diabetic group, and 3.6 % in the non-diabetic group, which was not statistically significant. During the trial, there were no systemic/neurovascular or device-related problems. ESWT appears effective in the treatment of chronic diabetic and non-diabetic foot ulcers, according to the study. However, the effects of ESWT substantially reduced from 1 to 5 years following treatment, and further research is required.

Systematic Reviews and Meta-Analyses

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 HBOT in 2 studies. The authors concluded that ESWT was associated with a greater reduction of the wound surface area, more effective than HBOT for treating DFUs, had an increase of re-epithelialization, 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.

Hitchman et al. (2019) in a systematic review, assessed the currently available evidence 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 (2022) 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 probably 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.

Zhang et al. (2017) published results of a systematic review and meta-analysis (n=7RCTs/301 subjects) to assess the effectiveness of ESWT compared to standard care treatment for the healing of chronic wounds. Studies were included in which at least 70% of participants completed the trial, and wound healing rates were recorded prospectively in terms of ESWT efficacy compared to standard wound care and monitored at least monthly during the entire trial. Follow-up occurred primarily over weeks versus months, ranging from seven weeks to 18 months. Outcomes were wound healing rate and time, percentage of the wound healing area, and adverse effects. Radial ESWT was used in 5/7 studies. The standard wound care protocol varied between studies. Compared with the control treatment, ESWT was found to significantly increase wound healing rate ($p=0.0003$), and the percentage of the wound healing area ($p<0.00001$). Wound healing time was also reduced by 19 days with ESWT treatment ($p<0.00001$). No serious complications or adverse effects were reported. Limitations include small sample sizes and short follow-up timeframe. Although the data suggests that ESWT as an adjunct to wound treatment could improve the healing process of chronic wounds compared

to standard treatment alone, additional, larger well-designed high-quality controlled trials with long-term follow-up are needed to determine the role of ESWT in chronic wound care.

Zhang et al. (2018) published an update to the earlier systematic review and meta-analysis that included acute soft tissue wounds as well as chronic wounds (n = 10 RCTs/473 patients) in establishing the effectiveness of ESWT over standard wound therapy. When compared to standard wound therapy alone, ESWT reduced wound-healing time for acute soft tissue wounds by 3 days ($p<0.001$). This update did not modify the conclusion since additional high-quality, well-controlled RCTs are required to assess the role of ESWT in acute and chronic soft tissue wounds.

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. There were no published studies that assessed the efficacy of dermaPACE in treating chronic wounds other than DFUs. Despite its intended usage to treat chronic wounds more broadly, the FDA has granted De Novo approval for dermaPACE only for the treatment of DFUs at this time.

International Working Group on Diabetic Foot (2019) issued a recommendation against the use of agents reported to influence wound healing through alteration of the physical environment including using electricity, magnetism, ultrasound, and shockwaves, in preference to best standard of care. (Strong recommendation, Low-quality evidence).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	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

8/09/2023	Policy reviewed and updated. No coverage criteria changes.
8/10/2022	Policy reviewed and updated. No coverage criteria changes.
8/11/2021	Policy reviewed. No changes in coverage criteria. Updated references.
8/10/2020	New Policy. IRO policy reviewed by practicing MD board-certified in Surgery General, Wound Care.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*