Subject: Extracorporeal Shockwave Therapy in the Treatment of Chronic Diabetic Foot Ulcers	Original Effective Date: 9/16/20
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Contents

RECOMMENDATION

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.

RECOMMENDATION

ESWT for diabetic foot ulcers (DFU) is not medically necessary due to inconclusive medical and scientific evidence in peer-reviewed medical literature and unproven beneficial effect on health outcomes.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Extracorporeal shock wave therapy (ESWT)

ESWT has been investigated as a treatment for various musculoskeletal conditions such as medial epicondylitis (i.e., golfer's elbow); calcific tendonitis of the rotator cuff; achilles and patellar tendonitis; avascular necrosis of the femoral head; diabetic foot ulcers and nonunion of fracture. However, ESWT devices are FDA approved for only three indications: plantar fasciitis (i.e., heel pain) lateral epicondylitis (i.e., tennis elbow) and chronic diabetic foot ulcers (DFU). **This policy addresses ESWT for the treatment of chronic DFUs only.**

ESWT is a non-invasive treatment that involves delivery of low- or high-energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft-tissue interface. The most common use for shock waves has been to break kidney stones into fragments that can then be passed (i.e., renal lithotripsy). Although the precise mechanism by which ESWT could provide a therapeutic effect is not known, it is thought that ESWT may decrease inflammation and induce neovascularization, allowing for improved perfusion and accelerated epithelialization. Both high-dose and low-dose focused ESWT have been utilized. Low-energy shock waves are applied in a series of treatments and do not typically cause any pain. High-energy shock wave treatments are generally given in one session and usually require some type of anesthesia [National Institute for Clinical Excellence (NICE), 2009b; 2012c]. A high-dose protocol consists of a single treatment of high-energy shock waves (1300mJ/mm^2) and a painful procedure that requires anesthesia. A low-dose protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia. Although the mechanisms by which ESWT improves ulcer healing are not fully understood, it is purported to stimulate vascular in-growth, neovascularization and cell proliferation, therefore improving healing rates in chronic ulcers.

Chronic diabetic foot ulcers (DFUs)

Chronic DFUs are defined as nonhealing ulcers of the foot lasting more than 3 months' duration in patients with diabetes. DFUs are classified as neuropathic (most common), ischemic, or neuroischemic depending on whether ulcer is associated with peripheral neuropathy and/or arterial disease. Risk factors for DFU include but are not limited to:

- peripheral neuropathy (motor, sensory, or autonomic) (most common)
- peripheral arterial disease
- neuropathic arthropathy (also known as Charcot neuroarthropathy)
- longer duration of diabetes (prevalence of peripheral neuropathy increases as the duration of the disease increases); however, in some patients, foot ulceration may be the presenting feature of type 2 diabetes
- end-stage renal disease, particularly if dialysis is required
- orthopedic abnormalities that alter biomechanics, resulting in areas of increased pressure on the foot
- foot trauma

DFUs occur in over 10% of diabetic patients and are associated with high morbidity. DFU is the most common precursor to amputation of the lower extremity and 85% of all lower extremity amputations in patients with diabetes reported to be proceeded by ulceration (Neville 2016). Goals of treatment include healing the ulcer, preventing secondary infection, preventing recurrence, and avoiding amputation (Armstrong et al. 2017). Important components of treatment for all ulcers, regardless of stage and depth is adequate debridement, proper local wound care (debridement and dressings), mechanical offloading (redistribution of pressure off wound to entire weight-bearing surface of foot), and control of infection and ischemia, when present.

U.S. Food and Drug Administration (FDA)

The dermaPACE System is a focused ESWT utilized for the treatment of DFUs. The dermaPACE system delivers a proprietary type of ESWT known as Pulsed Acoustic Cellular Expression (PACE) therapy. According to SANUWAVE Health, the PACE technology utilizes high-energy acoustic pressure waves in the shock wave spectrum to produce compressive and tensile stresses on cells and tissue structures to elicit a series of biological responses. PACE treatment results in increased circulation, biofilm disruption, cytokine and chemokine effects, growth factor upregulation, and angiogenesis which are many of the factors that lead to the subsequent regeneration of tissue such as skin, musculoskeletal, and vascular structures.

The dermaPACE System was reviewed through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices of a new type for which there is no legally marketed predicate device to which the device can claim substantial equivalence. FDA concluded that the dermaPACE System should be classified into Class II, and substantially equivalent devices of this generic type, into Class II. The FDA identifies this generic type of device as 'extracorporeal shock wave device for treatment of chronic wounds,' a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are generated inside the device and transferred to the body using an acoustic interface. Sanuwave Health received FDA approval for the dermaPACE System on December 28, 2017.

The dermaPACE System is indicated to deliver acoustic pressure shockwaves in the treatment of chronic, full-thickness DFUs 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 patients 22 years and older, presenting with DFUs lasting for more than 30 days, and should be used along with standard diabetic ulcer care. Treatment with dermaPACE, as an adjunct to standard wound care therapy, is generally provided in a physician's office or outpatient in 4 to 8 brief, non-invasive applications over 2 to 10 weeks. Monitoring and usual care are required afterward.

SUMMARY OF MEDICAL EVIDENCE

The Sanuwave Health dermaPACE® system received FDA clearance on December 28, 2017. This device provides 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 (aged 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. The FDA reviewed clinical data from two multi-center, randomized, double-blind studies with a total of 336 diabetic patients receiving either usual care plus the dermaPACE® System shockwave therapy or usual care plus sham shockwave therapy (Snyder et al. 2018)

The best available evidence is a single published report on 2 randomized, sham controlled trials of dermaPACE in patients with DFU; both trials failed to meet the primary efficacy endpoint of complete wound closure at 12 weeks (DERM01 and DERM02; Snyder et al., 2018). **There is insufficient published evidence to assess whether the addition of extracorporeal shockwave therapy (ESWT) with the dermaPACE system significantly expedites wound healing in patients with diabetic foot ulcers (DFU).**

Snyder et al. (2018) conducted two multicenter, prospective, controlled, double-blinded, randomized phase III clinical trials to investigate the efficacy of focused ESWT as an adjunctive treatment for neuropathic DFUs compared with sham treatment. The two studies evaluated 336 patients; 172 patients treated with active therapy and 164 managed with a sham device.

- Study 1 enrolled patients ≥ 18 years of age, and study 2 enrolled patients ≥ 22 years of age. Both studies included patients with at least one DFU in the ankle area or below that had persisted a minimum of 30 days prior to the screening visit. Participants could have more than one DFU, but only one was treated during this study.
- Prior to randomization, eligible patients were enrolled into a two-week run-in period during which standard care alone was delivered. Patients who achieved > 50% wound volume reduction were ineligible for randomization. This ensured that only patients whose wounds were unresponsive to standard care were randomized. In both studies, patients were randomized to either standard care with focused ESWT active therapy (pulsed acoustic cellular expression, dermaPACE System, SANUWAVE Health Inc.) (n=172, both studies combined), or standard care with sham therapy (n=164, both studies combined).
- Standard care included, but was not limited to, sharp debridement according to local practice, sterile saline-moistened gauze, adherent or non-adherent secondary dressings including foams and hydrocolloids, and pressure-reducing footwear. The use of antibacterial products was not permitted.
- Both active and sham therapy were administered four times in two weeks in study one and a maximum of eight times over 12 weeks in study two. Standard care continued in both studies throughout the 12-week treatment phase and followed patients up to 24 weeks.
- The primary outcome measured for both studies was the incidence of complete wound closure within 12 weeks.
- The secondary outcomes measured: target ulcer area, volume, depth and perimeter; rate of wound closure; mean wound area reduction; percentage of patients with an increase in wound area; rate of treatment emergent AEs, treatment emergent SAEs and device-related treatment emergent AEs; recurrence and amputation rate; rate of ESWT malfunctions; and changes in baseline values in wound pain assessed by VAS. The safety outcome was conducted on the pooled dataset and measured the rate of adverse events (AEs) at 24 weeks after initial application, including serious adverse events (SAEs), device-related AEs, and active therapy malfunctions throughout the application, treatment, and follow-up periods.
- **The primary outcome was not met in Study 1 or Study 2, nor was it met in the pooled analysis.** However, statistically significantly more DFU healed at 20 (35.5% versus 24.4%; p=0.027) and 24 weeks (37.8% versus 26.2%; p=0.023) in the active treatment arm compared with the sham-controlled arm.

Wang et al. (2014) published the results of a cohort study which evaluated the long-term outcomes of ESWT for chronic foot ulcers. The cohort consisted of 67 patients (n=72 ulcers) with 38 patients (n=40 ulcers) in the diabetes mellitus (DM) group and 29 patients (n=32 ulcers) in the non-diabetes mellitus (non-DM) group. The inclusion criteria included patients with recurrent or persistent nonhealing diabetic or nondiabetic ulcers of the foot for > 3 months. All patients received ESWT to the diseased foot using dermaPACE device (Sanuwave, Alpharetta, GA) twice per week for three weeks for a total of six treatments. The outcomes evaluated healing of chronic foot ulcers using clinical assessment and tissue viability measured by local blood flow perfusion scan preoperatively and postoperatively at six weeks, one year and five years. Other outcome measures were mortality and morbidity. There were tens patients lost to follow-up (n=9 DM group, n=1 non-DM group). The clinical results of the non-

DM group were significantly better than those of the DM group at three months (p=0.006), one year (p=0.027), and five years (p=0.022), respectively. The blood flow perfusion rates significantly improved in both DM and non-DM groups (p=0.011 and p=0.033) respectively. The improvements of blood flow perfusion rate began at six weeks and lasted for up to one year following ESWT. However, from 1–5 years the blood flow perfusion rate decreased in both groups. The non-DM group showed significantly better blood flow perfusion than the DM group at five years (p=0.04). The mortality rate was 15% in total series, 24% in the DM group, and 3% in the non-DM group from 1–5 years after treatment. The rate of amputation was 11% in total series, 17% in DM group, and 3.6% in non-DM group (p=0.194), not significant. There were no systemic/neurovascular or device related complications during the study. **The study concluded ESWT appears effective in the treatment of chronic diabetic and nondiabetic foot ulcers. However, the effects of ESWT significantly decreased from 1 to 5 years after treatment and additional studies are required.**

Wang et al. (2011) performed a prospective open-label, randomized study that compared the effectiveness of ESWT using the dermaPACE device (Sanuwave, Alpharetta, GA, USA) and hyperbaric oxygen therapy (HBOT) in chronic diabetic foot ulcers. Patients (n=87) were randomized to either the ESWT group (n=39 patients/44 feet) or the HBOT group (n=38 patients/40 feet). This study included patients with chronic non-healing diabetic foot ulcers for greater than three months duration. The healing of the ulcers was evaluated using clinical assessment, blood flow perfusion scan and histopathological examination. Clinical assessment of the ulcer status was performed by physical examination at three and six weeks, then once every three months and included visual observation and photo-documentation. Blood flow perfusion scan and histopathological examination were performed prior to the initiation of the treatment protocol and as part of the last examination. The clinical results after one treatment course showed completely healed ulcers in 57% and 25% (p=0.003); ≥ 50% improved ulcers in 32% and 15% (p=0.071); unchanged ulcers in 11% and 60% (p<0.001) for the ESWT group and the HBOT group, respectively. Twenty-seven patients also received a second course of treatment due to improved but incomplete healing of the ulcers 4–6 weeks from the first treatment. The results after a second course of treatment showed completely healed ulcers in 50% and 6% (p=0.005); ≥ 50% improved ulcers in 43% and 47% (p=0.815); unchanged ulcers in 7% and 47% (p=0.015) for the ESWT group and the HBOT group, respectively. Prior to the initiation of treatment, the blood flow perfusion rates were comparable between the two groups (p=0.245). The blood flow perfusion rates were significantly increased after ESWT (p<0.001), whereas, the changes after HBOT were not statistically significant (p=0.916). Following the treatment protocol, the difference in blood flow perfusion rate between the two groups became statistically significant favoring the ESWT group (p=0.002). In histopathological examination, the ESWT group showed considerable increases in cell proliferation, cell concentration and cell activity, and a decrease in cell apoptosis as compared to the HBOT group. Adverse events included four patients in the HBOT group developed middle ear barotraumas and sinus pain. The symptoms resolved spontaneously upon the release of the chamber air pressure. No other adverse events were related to neurovascular complications or device related problems. Author acknowledged limitations included: the small patient population, unblinding of patients and providers, different grades of ulcers, lack of long-term follow-up and use of only one type of shockwave device. **Although the results of the current study demonstrated that ESWT is more effective than HBOT in chronic diabetic foot ulcers, additional, larger well-designed controlled trials with long-term follow-up are needed to determine the role of ESWT in chronic non-healing diabetic foot ulcers.**

Systematic Review and Meta-Analysis

Hitchman et al. 2019, in a systematic review, assessed the currently available evidence examining the efficacy of ESWT on healing of DFU. The review included 5 trials of 255 patients published between 2009 and 2016. Three studies compared ESWT to standard wound care, and 2 studies compared ESWT to hyperbaric oxygen therapy (HBOT). All studies contained unclear to high risk of bias assessed by the Cochrane Risk of Bias Tool. ESWT was superior to standard wound care at complete wound healing (odds ratio [OR] 2.66 95% confidence interval [CI] 1.03, 6.87, I^2 0%) and time to healing (64.5 ± 8.06 days versus 81.17 ± 4.35 days). DFU healing improved more with ESWT than HBOT (OR 2.45 95% CI 1.07, 5.61 I^2 28%). There was variable evidence of effect on the blood flow perfusion rate. Infection rate and amputation rate were not reported. **This systematic review concludes that ESWT has the potential to improve healing in DFUs, although there is insufficient evidence to justify its use in routine clinical practice at this time.** The meta-analysis has a high risk of bias and is unlikely to reflect true effect size because of problematic risk of bias in included studies. This review highlights the variable quality of methodology of trials and dosing of shockwave therapy and the need for robust adequately powered research into this promising treatment.

Huang et al. (2019) performed a systematic review and meta-analysis of the evidence (n=8 RCTs/339 subjects) evaluating the efficacy of ESWT for treating foot ulcers in adults with type 1 and type 2 diabetes. Randomized controlled trials (RCTs) were eligible for inclusion if patients were 18 years of age or older with an active foot ulcer of neuropathic, neuroischemic or ischemic etiology (irrespective of type 1 or type 2 DM), the intervention group was treated with ESWT plus standard wound care (SWC) and the control group was treated with SWC or SWC plus HBOT. The SWC could involve blood sugar control, debridement, wound dressings, total contact casting or usual care, provided that the same concomitant treatment was used in both groups. Follow-ups ranged from five to 24 weeks. The outcomes measured were the reduction of wound surface area (WSA), percentage of re-epithelialization and population of complete cure. This study assessed both the pooled data of the three outcomes at the end of treatment and at the end of follow up. The ESWT group and the control group presented no statistically significant difference in WSA at the end of treatment ($p=0.087$). At the end of follow-up, ESWT was found to be associated with a clinically significant reduction of WSA by 1.54 cm2 ($p<0.001$). The meta-analysis demonstrated that ESWT can promote re-epithelialization by 18.65% at the end of treatment and 26.31% at the end of follow up and has higher effectiveness than control treatment for subjects ($p<0.001$ and $p<0.001$, respectively). ESWT significantly increased the population with complete cure at the end of treatment ($p<0.001$). However, there was no statistically significant difference at the end of follow up ($p=0.052$) between groups. Author noted limitations included the small sample size that only included patients with a DFU making it difficult to apply the result to the general population. **The authors concluded that ESWT is a feasible and safe adjuvant treatment option for patients with DFU. However, because of the complicated mechanism of DFU and the insufficient number of participants in the studies, more RCTs of high quality and with good control are required to evaluate the effectiveness of ESWT in 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.**

In 2018, Zhang et al. published an update to the previous systematic review and meta-analysis to include acute soft tissue wounds as well as chronic wounds (n=10 RCTs/473 subjects) in determining the effectiveness of ESWT compared to conventional wound therapy. ESWT reduced wound-healing time by three days ($p<0.001$) for acute soft tissue wounds when compared to CWT alone. **The conclusion remained unchanged with this addition, higher-quality and well-controlled RCTs are needed to further assess the role of ESWT for acute and chronic soft tissue wounds.**

Professional Society Guidelines

There are several guidelines on treatment of DFUs however do not address recommendations for ESWT.

International Working Group on Diabetic Foot (IWGDF 2019)

IWGDF recommends against using agents reported to have an effect on wound healing through alteration of physical environment including through use of shockwaves, in preference to best standard of care (IWGDF Strong recommendation, Low-quality evidence).

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound (Effective 01/01/2019)
0513T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure) (Effective 01/01/2019)

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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FDA

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Professional Society Guidelines

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Other Resources

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Review/Revision History:

8/10/2020: New Policy. Advanced Medical Review (AMR): Policy reviewed by practicing MD board-certified in Surgery General, Wound Care. 8/12/20