

Medical Policy Manual

Extracorporeal Shockwave Therapy

Policy Number: 0020

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Specialist Reviewer: Ryan Downey, DPM

BACKGROUND

CLINICAL BACKGROUND (*excerpted from INTC 2017*)

Extracorporeal shockwave therapy (ESWT) is based on the same mechanism of action as conventional shock wave treatment used to break kidney stones. Although the exact physiologic mechanism of effect for ESWT is unclear, it is thought that the shock waves work through direct and/or indirect effects that help to reduce pain transmission, break down calcium deposits and scarring, cause a temporary inflammatory response, and/or simulate healing of tissues. Therapy with ESWT usually consists of 1 to 3 sessions, during which 1000 to 3000 pulses of low- or high-energy shock waves are administered to the pain site. It is theorized that once the deposits are ablated, the associated pain subsides, and new blood vessel formation and tissue development follows.

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an NCD or LCD, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Extracorporeal Shockwave Therapy" for medical necessity determinations. Use the criteria below.

Extracorporeal shockwave therapy (ESWT) is considered experimental and investigational for all indications including (but not limited to) musculoskeletal conditions such as Achilles' tendonitis, plantar fasciitis, epicondylitis, as well as soft tissue indications, such as wounds and burns. There is insufficient evidence to determine whether ESWT is medically appropriate for any indication.

NOTE: This policy does not pertain to extracorporeal shock wave lithotripsy for treatment of kidney stones.

RATIONALE

EVIDENCE BASIS

The Kaiser Permanente Interregional New Technologies Committee (INTC) reviewed the evidence for extracorporeal shockwave therapy in 2017. Their findings include the following:

"Findings from existing systematic reviews and HTAs were mixed, with some authors concluding that the evidence base is conflicting, insufficient, limited, and/or weak, and others concluding that ESWT is an effective treatment for plantar fasciitis and is based on moderate- or high-quality evidence. Reviews with more positive results tended to focus on relatively high-energy ESWT and/or avoidance of anesthesia

during ESWT treatment. ESWT for treatment of plantar fasciitis appears to be reasonably safe, although few studies evaluated adverse events as outcomes.

In addition to existing systematic reviews and HTAs, evidence from randomized trials of patients with chronic plantar fasciitis that enrolled at least 100 patients were included. Based on these criteria, the body of evidence on ESWT for treatment of chronic plantar fasciitis includes 10 RCTs that evaluated ~2000 patients. In these RCTs, treatment with ESWT resulted in significantly improved overall pain, pain with daily activity, and pain with applied pressure compared to sham ESWT. However, findings were less consistent for other outcomes, including measures of function and pain with the first steps of the day. Although 10 randomized trials with more than 2000 patients were identified, the overall quality of evidence is low-to-moderate given the relatively small sample size, variations in treatment protocols, and inconsistencies in findings across outcomes.

Most of the studies used a double-blind, sham-controlled study design. Most studies used focused ESWT (as opposed to radial ESWT), although specific treatment parameters varied considerably across studies (e.g., energy flux density [EFD], number of pulses, number of ESWT sessions). Despite limiting enrollment to patients with treatment-refractory, chronic plantar fasciitis, several studies noted that sham patients had substantial improvements compared to baseline. Seven of the 10 studies had some industry affiliation, including 1 or more co-authors currently or formerly employed by a device manufacturer and/or manufacturer-supposed equipment or funding.

The overall body of evidence on ESWT for treatment of wounds, ulcers, or burns includes 10 comparative studies of 473 wounds, ulcers, or burns. In these controlled studies, treatment with ESWT plus standard wound care resulted in significantly improved wound healing compared to either standard wound care alone or hyperbaric oxygen therapy (HBOT) plus standard wound care. Despite clinically heterogeneous study populations and treatment protocols, results were consistent across studies. ESWT for ulcers, wounds, and burns appears to be reasonably safe, although few studies evaluated adverse events as outcomes.

Although many of the studies found statistically significant differences in wound healing outcomes for ESWT versus standard wound care, the overall precision is poor due to the small total sample size (473 wounds, ulcers, or burns). There was notable clinical heterogeneity across studies and the findings for any single indication and treatment protocol are even more limited. Two studies had poor results reporting in which results were not clearly presented and/or data discrepancies were observed for text, tables, and figures. Two studies had inadequate randomization (e.g., based on odd vs. even days of week). Three studies excluded randomized patients with poor compliance or incomplete follow-up data. One study was terminated early due to apparent benefit of ESWT and the published results were from an unscheduled interim analysis. Nine of the 10 studies had some industry affiliation, including 1 or more co-authors currently or formerly employed by a device manufacturer and/or manufacturer-supposed equipment or funding.

Overall, these promising but preliminary findings suggest that ESWT plus standard wound care may result in improved wound healing compared to either standard wound care alone or HBOT plus standard wound care. Although 9 randomized trials were identified, the overall quality of evidence is low given the limitations of the included studies. Additional randomized, double-blind trials are needed to confirm these findings. Clinical input gathered on this topic was consistent with this review. SCPMG is considering an IRB-approved study as some clinicians have some experience with the technology and consider ESWT as a potential alternative to surgery in some patients with chronic plantar fasciitis."

CODES

CPT Code	Description
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving humeral epicondyle

0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care, each additional wound
0512T-0513T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

REFERENCES

Interregional New Technologies Committee (2017). Extracorporeal Shockwave Therapy.