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Subject: Extracorporeal Shock Wave (ESW) for Treatment of Plantar Fasciitis and Other Musculoskeletal Conditions

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Extracorporeal shock wave therapy (ESWT) is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated, (eg, the heel in the case of plantar fasciitis). Shock waves are generated at high- or low-energy intensity, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

Summary and Analysis of Evidence: Gollwitzer et al (2015) reported on results of a sham-controlled randomized trial, with patients and outcome assessments blinded, evaluating ESWT for plantar fasciitis present for at least 6 months and refractory to at least 2 nonpharmacologic and 2 pharmacologic treatments. A total of 250 subjects were enrolled (126 in the ESWT group, 124 in the placebo group). The trial's primary outcome was an overall reduction of heel pain, measured by percentage change of the VAS composite score at 12 weeks. Median decrease for the ESWT group was -69.2% and -34.5% for the placebo group (effect size, 0.603; $p=.003$). Secondary outcomes included success rates defined as decreases in heel pain of at least 60% from baseline. Secondary outcomes generally favored the ESWT group. Most patients reported satisfaction with the procedure. Strengths of this trial included an intention-to-treat analysis, use of validated outcome measures, and at least some reporting of changes in success rates (rather than percentage decrease in pain) for groups. There was some potential for bias because treating physicians were unblinded. In a double-blind RCT, Bahar-Ozdemir et al (2021) evaluated the effects of ESWT alone ($n=15$), ESWT plus low-dye kinesiotaping ($n=15$), and ESWT plus sham kinesiotaping ($n=15$) in 45 patients with plantar fasciitis. Main outcome measures included VAS change, the heel tenderness index, and foot function index. Low-dye kinesiotaping plus ESWT was more effective on foot function improvement than ESWT and sham kinesiotaping or ESWT alone in the 4 week

duration of follow-up. However, the combination did not provide a significant benefit on pain and heel tenderness due to plantar fasciitis. Randomized controlled trials comparing ESWT and radial shock wave (RSW) with corticosteroid injection and conservative treatment (exercise, orthotic support) have been performed, with mixed findings (Xu et al, 2020; Lai et al, 2018; Eslamain et al, 2016). As the follow-up period for these studies are 3 months or less, the clinical significance of these results are uncertain (Cinar et al, 2018). One RCT found that ESWT plus stretching exercises had similar efficacy to instrument-assisted soft-tissue mobilization plus stretching exercises through 8 weeks of follow-up, but at 6 months soft-tissue mobilization was more effective than ESWT (Pisirici et al, 2022).

A meta-analysis by Karanasios et al (2021) of 27 randomized trials (N=1871) found that ESWT (alone or as an additive intervention) compared with sham or other control treatment in patients with lateral elbow tendinopathy did not provide clinically meaningful improvement in pain intensity, elbow disability, or grip strength. A systematic review and network meta-analysis by Liu et al (2022) of 40 RCTs found that ESWT was the optimal intervention for improving short-term and medium-term grip strength compared to several injection therapies. Yang et al (2017) published results from an RCT (N=30) comparing RSW plus physical therapy with physical therapy alone in patients with lateral epicondylitis. Outcomes included VAS pain and grip strength. Significant differences were seen in grip strength by 12 weeks of follow-up; the mean difference in grip strength between groups was 7.7 (95% CI, 1.3 to 14.2), favoring RSW. Significant differences in VAS pain (10- point scale) were not detected until 24 weeks of follow-up; the mean difference between groups was -1.8 (95% CI, -3.0 to -0.5), favoring RSW.

A systematic review and network meta-analysis of RCTs by Arirachakaran et al (2017) evaluated ESWT, ultrasound-guided percutaneous lavage (UGPL), subacromial corticosteroid injection (SAI), and combined treatments for rotator cuff calcific tendinopathy. The literature search, conducted through September 2015, identified 7 RCTs for inclusion. Six of the trials had ESWT as 1 treatment arm, with the following comparators: placebo (4 trials), UGPL plus ESWT (1 trial), and UGPL plus SAI (1 trial). One trial compared UGPL plus SAI with SAI alone. Outcomes were Constant-Murley Score (CMS) (5 trials), VAS pain (5 trials), and size of calcium deposit (4 trials). Network meta-analysis results are summarized below: VAS pain: ESWT, UGPL plus SAI, and SAI alone were more effective in reducing pain than placebo. Compared with each other, ESWT, UGPL plus SAI, and SAI alone did not differ statistically. CMS: ESWT was statistically more effective than placebo. No other treatment comparisons differed statistically. Size of calcium deposit: UGPL plus SAI was statistically more effective than placebo and SAI alone. ESWT was statistically better than SAI alone, but not more effective than placebo.

In a systematic review and meta-analysis, Ioppolo et al (2013) identified 6 RCTs that compared ESWT with sham treatment or placebo for calcific shoulder tendinopathy. Greater shoulder function and pain improvements were reported at 6 months with ESWT than placebo. Most studies were considered low quality.

Mani-Babu et al (2015) reported on results of a systematic review of studies evaluating ESWT for lower limb tendinopathies. Reviewers included 20 studies, 11 of which evaluated ESWT for Achilles tendinopathy (5 RCTs, 4 cohort studies, 2 case-control studies). In the pooled analysis, reviewers reported that evidence was limited, but showed that ESWT was associated with greater short-term (<12 months) and long-term (>12 months) improvements in pain and function compared with nonoperative treatments, including rest, footwear modifications, anti-inflammatory medication, and gastrocnemius soleus stretching and strengthening. Reviewers noted that findings from RCTs of ESWT for Achilles

tendinopathy were contradictory, but that some evidence supported short-term improvements in function with ESWT. Reviewers warned that results be interpreted cautiously due to heterogeneity in patient populations (age, insertional versus mid-portion Achilles tendinopathy) and treatment protocols. Al-Abbad and Simon (2013) conducted a systematic review of 6 studies on ESWT for Achilles tendinopathy. Selected for the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found in 4 studies demonstrating the effectiveness of ESWT in the treatment of Achilles tendinopathy at 3 months. However, 2 RCTs found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy (Rasmussen et al, 2008; Costa et al, 2005).

The trials on the use of ESWT for patellar tendinopathy have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. An RCT by Thijs et al (2017) compared the use of ESWT plus eccentric training (n=22) with sham shock wave therapy plus eccentric training (n=30) for the treatment of patellar tendinopathy. Patients were physically active with a mean age of 28.6 years (range, 18 to 45 years). ESWT and sham shock wave were administered in 3 sessions, once weekly. Patients were instructed to perform eccentric exercises, 3 sets of 15 repetitions twice daily for 3 months on a decline board at home. Primary outcomes were Victorian Institute of Sport Assessment-Patellar score and pain score during functional knee loading tests (10 decline squats, 3 single leg jumps, 3 vertical jumps). Measurements were taken at baseline, 6, 12, and 24 weeks. There were no statistically significant differences between the ESWT and sham shock wave groups for any of the primary outcome measurements at any follow-up except for the vertical jump test at week 6. In an RCT of patients with chronic patellar tendinopathy (N=46), despite at least 12 weeks of nonsurgical management, Smith and Sellon (2014) reported that improvements in pain and functional outcomes were significantly greater ($p<.05$) with plasma-rich protein injections than with ESWT at 6 and 12 months, respectively.

Evidence for the use of ESWT for medial tibial stress syndrome includes a small RCT (Newman et al, 2017) and a small nonrandomized study (Rompe et al, 2010). The RCT showed no differences in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limited the strength of the conclusions.

In their meta-analysis, Hao et al (2018) compared the effectiveness of ESWT with other treatment strategies in improving pain scores and Harris Hip Score (HHS) for patients with osteonecrosis of the femoral head. Their search for interventional studies published in Chinese or English yielded 4 articles with a total of 230 patients, most of whom were in stages I through III of osteonecrosis of the femoral head. Before treatment, no significant differences in pain scores ($p=.1328$) and HHS ($p=.287$) were found between the ESWT group (n=130) and control group (n=110). Post-treatment, the ESWT group reported significantly higher improvement in pain scores than the control group (standard mean difference, -2.1148; 95% CI, -3.2332 to -0.9965; $Z=3.7063$; $p=.0002$), as well as higher HHSs (standard mean difference, 2.1377; 95% CI, 1.2875 to 2.9880; $Z=4.9281$; $p<.001$). However, the analysis revealed no significant improvements in pain scores before and after treatment ($p=.005$), but it did reveal significant improvements in the HHS ($p<.001$). Patient follow-up time across studies ranged from 3 to 25 months. This analysis had several limitations including: only 1 RCT was included out of 4 studies; small sample size resulted in more pronounced heterogeneity between studies; the studies were of poor quality; publication bias was detected for the HHS after treatment; and only 2 studies reported pain scores.

Sansone et al (2022) published a systematic review and meta-analysis involving 23 studies that evaluated the effectiveness of ESWT in the treatment of nonunion fracture in long bones. The review

included 2 RCTs, a single non-randomized controlled trial, and 20 observational studies (14 retrospective; 6 prospective), with a total of 1838 cases of delayed union or nonunion. Only data for 1200 of the 1838 cases were included in the meta-analysis since several studies did not separate results from long bones from those of other bones. Healing occurred in 876 (73%) of the 1200 total long bones after ESWT. Hypertrophic cases were associated with a 3-fold higher healing rate as compared to oligotrophic or atrophic cases ($p=.003$). Bones in the metatarsal region were the most receptive to ESWT with a healing rate of 90%, followed by the tibiae (75.5%), femurs (66.9%), and humeri (63.9%). Increased healing rates were observed among patients who had shorter periods between the injury and ESWT ($p<.02$). Six months of follow-up was generally too brief to fully evaluate the healing potential of ESWT with several studies demonstrating increasing healing rates at follow-ups beyond 6 months after the last ESWT. Limitations included that the authors in 7 included studies did not distinguish between delayed union and nonunion when describing the patient population. In several other studies, the patient population was described clearly; however, data from delayed unions and nonunions were reported together. Incomplete data reporting also contributed to a lack of identifying and differentiating treatment protocols for ESWT.

Mihai et al (2021) performed a meta-analysis of 7 RCTs to estimate the effect of ESWT on lower limb poststroke spasticity at long-term follow-up (≥ 3 weeks after treatment). Compared with control, ESWT did not significantly improve Modified Ashworth Scale score at up to 12 weeks (7 studies; $N=146$; standardized mean difference, 0.32; 95% CI, -0.01 to 0.65; $I^2=0\%$) or VAS score at up to 12 weeks (2 studies; $N=50$; standardized mean difference, 0.35; 95% CI, -0.21 to 0.91; $I^2=0\%$), but did significantly improve passive range of motion at up to 12 weeks (3 studies; $N=69$; standardized mean difference, 0.69; 95% CI, 0.20 to 1.19; $I^2=0\%$). Limitations of this meta-analysis include the small number of available studies, as well as small sample sizes. Brunelli et al (2022) conducted a pilot RCT in 40 patients with poststroke spasticity. Patients were randomized to radial shock wave (RSW) or conventional physiotherapy and assessed for change in Modified Ashworth Scale scores of the shoulder, elbow, and wrist. Follow-up occurred at 1 month after the last RSW session. Significant differences in Modified Ashworth Scale elbow scores were noted after the second RSW session and remained until the end of follow-up. Scores at the shoulder were only significantly better in the RSW group at the 1-month follow up. Limitations of both studies included small sample size.

ESWT has been investigated in small studies for other conditions, including coccydynia in a case series of 2 patients (Marwan et al, 2014), and an RCT involving 34 patients, (Ahadi et al, 2022), painful neuromas at amputation sites in an RCT assessing 30 subjects, (Yung et al, 2014), and chronic distal biceps tendinopathy in a case-control study of 48 patients. Furia et al, 2017). The systematic review of ESWT for lower-extremity tendinopathies (previously described) by Mani-Babu et al (2015) reviewed 2 studies of ESWT for greater trochanteric pain syndrome, including 1 quasi-RCT comparing ESWT with home therapy or corticosteroid injection and 1 case-control study comparing ESWT with placebo. ESWT was associated with some benefits compared with placebo or home therapy.

POSITION STATEMENT:

Extracorporeal shock wave therapy (ESWT) (high-dose energy or low-dose energy), radial wave extracorporeal shock wave therapy, extracorporeal pulse activation therapy (EPAT®) and Pulsed Acoustic Cellular Expression (PACE™) therapy are considered **experimental or investigational** as a treatment of any musculoskeletal condition, including but not limited to:

- Plantar fasciitis
- Tendinopathies, including tendinitis of the shoulder
- Achilles tendinitis
- Tendinitis of the elbow (lateral epicondylitis)
- Patellar tendinitis
- Stress fractures
- Avascular necrosis of the femoral head
- Delayed union and non-union of fractures
- Spasticity

There is a lack of scientific evidence to permit conclusions on efficacy and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified (Investigational)
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle (Investigational)
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 (Investigational)

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

Achilles tendinitis: Located at the Achilles tendon; symptoms usually present as pain or stiffness 2-6 cm above the posterior calcaneus.

Avascular necrosis (AVN) of the femoral head: A pathologic process that results from interruption of blood supply to the bone. It is also called aseptic necrosis or osteonecrosis.

Delayed union: A fracture that fails to consolidate (unite) within normal limits, less than 9 months (i.e., healing has slowed with no indications that union will fail).

Lateral epicondylitis: Located at the lateral elbow (insertion of wrist extensors); symptoms include tenderness over the lateral epicondyle and proximal wrist extensor muscle mass, pain with resisted wrist extension with elbow in full extension, and/or pain with passive terminal wrist flexion with elbow in full extension.

Nonunion: A fracture site that shows no visibly progressive signs of healing after 3 months or more, as confirmed by serial radiographs (i.e., bone healing has ceased).

Patellar tendinopathy: Located at the proximal tendon at the lower pole of the patella; symptoms include pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear.

Plantar fasciitis: A common ailment characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain persists, interrupting activities of daily living.

Shoulder tendinopathy: Located at the rotator cuff muscle tendons, most commonly supraspinatus; symptoms usually present as pain with overhead activity.

Spasticity: A motor disorder characterized by increased velocity-dependent stretch reflexes. It is one characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

Tendonitis, Tendinitis: An inflammation of a tendon.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

09/27/01	New Medical Coverage Guideline.
04/25/02	Annual review.
01/01/03	HCPCS coding update.
04/15/03	Reviewed; no changes.
01/01/04	HCPCS coding update. Changed the policy number from 09-E0000-39 to 02-20000-24.
04/15/04	Scheduled review and revision to guideline; consisting of updated references.
07/01/05	3rd quarter HCPCS coding update; consisting of revision of code 0019T and addition of code 0101T and 0102T.
10/15/05	Scheduled review and revision of guideline; consisting of updated references.
01/01/06	Annual HCPCS coding update consisting of the deletion of codes G0279 – G0280 and the addition of code 28890.
10/15/06	Scheduled review and revision of guideline consisting of updated references and maintaining investigational statement.
07/15/07	Annual review; investigational status maintained, guideline reformatted, references updated.
10/15/08	Scheduled review; no change in position statement. Update references.
10/15/09	Scheduled review; no change in position statement. Update description section and references.
10/15/11	Scheduled review; no change in position statement. Updated description section and references.
01/01/13	Annual CPT coding update. Revised code descriptor for 28890.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
01/01/17	Annual CPT/HCPCS update. Deleted 0019T.
09/15/17	Scheduled review. Revised description, added additional indications considered investigational (Achilles tendinitis, patellar tendinitis, and spasticity). Revised definitions. Updated references.
02/15/20	Scheduled review. Revised description and Medicare Advantage program exception, reformatted position statement, and updated references.
10/15/21	Scheduled review. Maintained position statement and updated references.
01/01/22	Annual CPT/HCPCS coding update. Revised descriptor 0101T and 0102T.
05/23/23	Update to Program Exceptions section.
10/15/23	Scheduled review. Maintained position statement and updated references.

08/15/24	Scheduled review. Revised description, maintained position statement and updated references.
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