

MEDICAL POLICY No. 91527-R3

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT)

Effective Date: March 1, 2025

Review Dates: 4/07, 2/08, 2/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23, 2/24, 2/25 Status: Current

Date of Origin: April 11, 2007 Related policies: Foot Care # 91121

Summary of Changes

• Addition: Low intensity ESWT for the treatment of erectile dysfunction is considered experimental and investigational.

I. POLICY/CRITERIA

- 1. Extracorporeal Shock Wave Therapy (ESWT) is not medically necessary for the following conditions:
 - a. Orthopedic or musculoskeletal applications including but not limited to plantar fasciitis, wound healing, epicondylitis of the elbow due to insufficient evidence of the effectiveness of ESWT on musculoskeletal conditions or tissue injuries.
- 2. Low intensity ESWT (Li-ESWT) is considered experimental and investigation for the treatment of erectile dysfunction.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the <u>Priority Health Provider Manual</u>.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ***** HMO/EPO: This policy applies to insured HMO/EPO plans.
- * POS: This policy applies to insured POS plans.
- PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.



- INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html</u>. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html</u>, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. DESCRIPTION

Extracorporeal shock wave therapy (ESWT) is a non-invasive treatment using lowor high-energy pulses from 3-dimensional acoustic energy or shock waves, which can be focused and then propagated through water within body tissues (Schmitz et al., 2013). ESWT is performed in an outpatient setting, usually with the use local anesthesia or a regional block. ESWT has been used in the treatment of musculoskeletal conditions that are not responsive to conservative measures with the goal of reducing pain and promoting healing of the affected soft tissue. ESWT is intended as a noninvasive alternative to surgical treatment for chronic plantar fasciitis, chronic epicondylitis of the elbow, and other chronic musculoskeletal conditions. Chronic musculoskeletal conditions include a wide range of inflammatory and degenerative conditions of the musculoskeletal system. These disorders sometimes respond poorly to conservative treatments such as rest, medications, physical therapy, and/or corticosteroid injections. Surgery is an option but involves recovery time and possible morbidity. ESWT has also been proposed as a treatment for various chronic orthopedic conditions including tendonitis of the shoulder. Current theories include stimulation of healing after increased release of growth factors and neovascularization in the environment of local tissue injury. Many of these trials are not of sufficient quality to provide a reliable assessment of the effectiveness of ESWT (Wright, 2009). There are no established treatment protocols for ESWT, including energy density, number of sessions and shocks used, localization of shock waves, and whether local anesthesia is used.

Plantar fasciitis, also referred to as heel spurs, is thought to result from a biomechanical imbalance that puts abnormal tension on the plantar fascia, causing inflammation of the fascia, and tension on the calcaneal periosteum. Shock waves may be focused or radial. Focused shock waves are capable of high tissue penetration and may be generated using electrohydraulic, electromagnetic, or piezoelectric technology. Both focused and radial ESWT have been proposed as

treatments for plantar fasciitis. Radial ESWT uses pneumatic waves generated from air pressure that causes a projectile to hit the end of the applicator at high speed. Pneumatic devices deliver radially expanding shock waves to a wider area at a relatively low energy level (Dizon et al., 2013; Schmitz et al., 2013; Lohrer et al., 2016). It is hypothesized that the shock waves may reduce transmission of pain signals from sensory nerves in the plantar fascia through the rapid buildup of positive pressure or a more indirect effect through the implosion of bubbles in the interstitial fluid, causing calcium deposits to disintegrate, break down scarring, leading to transient inflammatory response, and/or stimulate tissue healing (Perez et al., 2003; Roehrig et al., 2005. However, the mechanism by which ESWT provides benefit is investigational because there are no established treatment parameters for ESWT. Substantial heterogeneity in treatment protocols and outcome measures used to assess efficacy of ESWT contribute to the inconsistent findings across studies. Additionally, there is insufficient evidence concerning the long-term safety and efficacy.

Low-intensity extracorporeal shockwave therapy (Li-ESWT), a form of ESWT, has been proposed as a treatment for erectile dysfunction (ED). It is proposed that increased penile angiogenesis induced by Li-EWST may increase penile blood flow and erectile function. A major limitation to most Li-ESWT studies is the lack of randomization to a sham control cohort, most studies include small and heterogeneous cohorts. There are currently three types of Li-ESWT generators available on the market: electrohydraulic, electromagnetic, and piezoelectric (Liu, 2021). Studies have varied by shockwave generator types and protocols (e.g., energy settings, dosing, frequency of use, probe locations, and duration of therapy) thereby making comparison difficult. Clinical practice guidelines and position statements, guidance appears to confer no or unclear support for Li-ESWT for treatment of ED. The AUA considers Li-EWST investigational for men with ED (Burnett, 2018). <u>Sexual Medicine Society of North America (SMSNA)</u> holds the position that there is an absence of robust clinical trial data supporting restorative therapies' efficacy in humans (Liu, 2021).

V. CODING INFORMATION

CPT/HCPCS Codes

Not covered for any indication:

- 0101T Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
- 0102T Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle
- 0512T Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound

- 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)
- 0864T Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy
- 28890 Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
- 28899 Unlisted procedure, foot or toes (*Explanatory notes must accompany claim*)
- 20999 Unlisted procedure, musculoskeletal system, general *(Explanatory notes must accompany claim)*

VI. REFERENCES

- 1. Abdelkader NA, Helmy MNK, Fayaz NA, Saweeres ESB. Short- and Intermediate-Term Results of Extracorporeal Shockwave Therapy for Noninsertional Achilles Tendinopathy. Foot Ankle Int. 2021 Jun;42(6):788-797.
- Aguilera-Sáez J, Dos Santos BP, Serracanta J, Monte-Soldado A, Bosacoma P, Rivas-Nicolls D, et al. The effect of Extracorporeal Shock Wave Therapy in the treatment of burn scars: A prospective, randomized, controlled trial. Burns. 2022 May;48(3):577-584.
- Aldajah S, Alashram AR, Annino G, Romagnoli C, Padua E. Analgesic Effect of Extracorporeal ShockWave Therapy in Individuals with Lateral Epicondylitis: A Randomized Controlled Trial. J Funct Morphol Kinesiol. 2022 Mar 18;7(1):29.
- 4. Angileri HS, Gohal C, Comeau-Gauthier M, et al. Chronic calcific tendonitis of the rotator cuff: a systematic review and meta-analysis of randomized controlled trials comparing operative and nonoperative interventions. J Shoulder Elbow Surg. 2023;32(8):1746-1760
- 5. Brindisino F, Marruganti S, Lorusso D, Cavaggion C, Ristori D. The effectiveness of extracorporeal shock wave therapy for rotator cuff calcific tendinopathy. A systematic review with meta-analysis. Physiother Res Int. 2024;29(3):e2106
- 6. Brunckhorst O, Wells L, Teeling F, Muir G, Muneer A, Ahmed K. A systematic review of the long-term efficacy of low-intensity shockwave therapy for vasculogenic erectile dysfunction. *Int Urol Nephrol.* 2019;51(5):773-781.
- Burnett AL, Nehra A, Breau RH, Culkin DJ, Faraday MM, Hakim LS, Heidelbaugh J, Khera M, McVary KT, Miner MM, Nelson CJ, Sadeghi-Nejad H, Seftel AD, Shindel AW. Erectile Dysfunction: AUA Guideline. J Urol. 2018 Sep;200(3):633-641. doi: 10.1016/j.juro.2018.05.004. Epub 2018 May 7. Erratum in: J Urol. 2022 Mar;207(3):743.
- 8. Campbell JD, Trock BJ, Oppenheim AR, Anusionwu I, Gor RA, Burnett AL. Meta-analysis of randomized controlled trials that assess the efficacy of low-

intensity shockwave therapy for the treatment of erectile dysfunction. Ther Adv Urol. 2019 Mar 29;11:1756287219838364.

- 9. Cole, C., et al., Plantar Fasciitis: Evidence-Based Review of Diagnosis and Therapy, American Family 2005; 72: 2237-2242.
- 10. Deu, R. S., and P. J. Carek, Common Sports Injuries: Upper Extremities, Rheumatology, Vol. 7, No. 2, 249-265, June 2005.
- 11. Dizon JN, Gonzalez-Suarez C, Zamora MT, Gambito ED. Effectiveness of extracorporeal shock wave therapy in chronic plantar fasciitis: a meta-analysis. Am J Phys Med Rehabil. 2013;92(7):606-620.
- 12. Forogh B, Karami A, Bagherzadeh Cham M. Effect of extracorporeal shock wave therapy and ultrasound-guided percutaneous lavage in reducing the pain of rotator cuff calcific tendinopathy; an updated systematic review and meta-analysis. J Orthop. 2024;56:151-160
- Gezginaslan Ö, Başar G. Comparison of Effectiveness of Density and Number of Sessions of Extracorporeal Shock Wave Therapy in Plantar Fasciitis Patients: A Double-Blind, Randomized-Controlled Study. J Foot Ankle Surg. 2021 Mar-Apr;60(2):262-268. doi: 10.1053/j.jfas.2020.08.001. Epub 2020 Aug 7. PMID: 33191061.
- 14. Glazer, G., and R. Hosey, Soft-tissue injuries of the lower extremity, Primary Care: Clinics in Office Practice, 31 (2004) 1005-1024.
- 15. Goldstein SW, Kim NN, Goldstein I. Randomized trial of low intensity shockwave therapy for erectile dysfunction utilizing grayscale ultrasound for analysis of erectile tissue homogeneity/inhomogeneity. Transl Androl Urol. 2024;13(10):2246-2267.
- Hayes, Inc. Extracorporeal Shock Wave Therapy for Calcific Tendonitis of the Shoulder. Evidence Analysis Research Brief, Sep 8, 2020; Annual Review August 13, 2024
- Hayes, Inc. Focused Extracorporeal Shock Wave Therapy For Chronic Plantar Fasciitis. Health Technology Assessment, Oct 6, 2016; Annual Review Jan 3. 2020; Annual Review Feb 3, 2021
- Hayes, Inc. Radial Extracorporeal Shock Wave Therapy For Chronic Plantar Fasciitis. Health Technology Assessment, Nov10, 2016; Annual review Feb 6, 2020; Annual Review March 23, 2021
- 19. Hinojosa-Gonzalez DE, Talamas Mendoza A, Torres-Martinez M, et al. Indirect assessment of low-intensity shockwave therapy's energy density and pulse frequency for erectile dysfunction: a systematic review, bayesian network meta-analysis and meta-regression. Int J Impot Res. 2024.
- 20. Kalyvianakis D, Hatzichristou D. Low-intensity shockwave therapy improves hemodynamic parameters in patients with vasculogenic erectile dysfunction: a triplex ultrasonography-based sham-controlled trial. J Sex Med. 2017;14(7):891-897.
- 21. Kennady EH, Bryk DJ, Ali MM, et al. Low-intensity shockwave therapy improves baseline erectile function: a randomized sham-controlled crossover trial. Sex Med. 2023;11(5):

- 22. Lange M, Charles D, Kazeem A, et al. Is low-intensity shockwave therapy for erectile dysfunction a durable treatment option?-long-term outcomes of a randomized sham-controlled trial. Transl Androl Urol. 2024;13(10):2194-2200.
- 23. Liu JL, Chu KY, Gabrielson AT, Wang R, Trost L, Broderick G, Davies K, Brock G, Mulhall J, Ramasamy R, Bivalacqua TJ. Restorative Therapies for Erectile Dysfunction: Position Statement From the Sexual Medicine Society of North America (SMSNA). Sex Med. 2021 Jun;9(3):100343.
- Lohrer H, Nauck T, Korakakis V, Malliaropoulos N. Historical ESWT Paradigms Are Overcome: A Narrative Review. Biomed Res Int. 2016;2016:3850461. doi: 10.1155/2016/3850461. Epub 2016 Jul 17. PMID: 27493955; PMCID: PMC4967434.
- Marks, W., et al., Extracorporeal Shock-Wave Therapy (ESWT) Emitted by New Generation Pneumatic Device in Treatment of Chronic Soft Tissue Disorder – Clinical, Preliminary Study, Journal of Orthopedics, 2005; 2 (6) e3.
- 26. Mykoniatis I, Pyrgidis N, Zilotis F, et al. The effect of combination treatment with low-intensity shockwave therapy and tadalafil on mild and mild-to-moderate erectile dysfunction: a double-blind, randomized, placebo-controlled clinical trial. J Sex Med. 2022;19(1):106-115.
- 27. Ong WLK, Lechmiannandan S, Lim YL, Manoharan D, Lee SB. Early outcomes of short-course low intensity shockwave therapy (LISWT) for erectile dysfunction: a prospective, randomized, double-blinded, sham-controlled study in malaysia. Andrologia. 2022;54(9):e14518.
- 28. Öztürk Durmaz H, Tuncay F, Durmaz H, Erdem HR. Comparison of Radial Extracorporeal Shock Wave Therapy and Local Corticosteroid Injection Effectiveness in Patients With Carpal Tunnel Syndrome: A Randomized Controlled Study. Am J Phys Med Rehabil. 2022 Jul 1;101(7):685-692.Perez M, Weiner R, Gilley JC. Extracorporeal shock wave therapy for plantar fasciitis. Clin Podiatr Med Surg. 2003;20(2):323-334.
- 29.
- 30. Raissi GR, Ghazaei F, Forogh B, Madani SP, Daghaghzadeh A, Ahadi T. The Effectiveness of Radial Extracorporeal Shock Waves for Treatment of Carpal Tunnel Syndrome: A Randomized Clinical Trial. Ultrasound Med Biol. 2017 Feb;43(2):453-460.Roehrig GJ, Baumhauer J, DiGiovanni BF, Flemister AS. The role of extracorporeal shock wave on plantar fasciitis. *Foot Ankle Clin.* 2005;10(4):699-712
- 31. Roerdink RL, Dietvorst M, van der Zwaard B, van der Worp H, Zwerver J. Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review. Int J Surg. 2017 Oct;46:133- 145.Schmitz C, Csaszar NB, Rompe JD, Chaves H, Furia JP. Treatment of chronic plantar fasciopathy with extracorporeal shock waves (review). J Orthop Surg Res. 2013;8:31.
- Sems A, Dimeff R, Iannotti JP. Extracorporeal shock wave therapy in the treatment of chronic tendinopathies. J Am Acad Orthop Surg. 2006;14(4):195-204.

Page 6 of 8

- Sighinolfi MC, Eissa A, Bellorofonte C, et al. Low-intensity extracorporeal shockwave therapy for the management of postprostatectomy erectile dysfunction: a systematic review of the literature. Eur Urol Open Sci. 2022;43:45-53.
- 34. Soohoo NF, Behren C CALEB BEHREND, Chapter 67 What Is the Best Treatment for Plantar Fasciitis?, Editor(s): Wright JC, Ahn H, Graham B, Howard A, Kreder HJ, Lau TCK, Lin SS, Mahomed NN, Whelan D, Evidence-Based Orthopaedics, W.B. Saunders, 2009, Pages 435-440.
- 35. Speed CA, Nichols D, Wies J, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. J Orthop Res. 2003;21(5):937-940.
- 36. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ankle Int. 2004;25(5):290-297.
- Whaley, A., and C. Baker, Lateral epicondylitis, Clinics in Sports Medicine, 23 (2004) 677-691.
- Xue X, Song Q, Yang X, et al. Effect of extracorporeal shockwave therapy for rotator cuff tendinopathy: a systematic review and meta-analysis [published correction appears in BMC Musculoskelet Disord. 2024 Jul 1;25(1):507. doi: 10.1186/s12891-024-07611-x]. BMC Musculoskelet Disord. 2024;25(1):357.
- 39. Yao H, Wang X, Liu H, Sun F, Tang G, Bao X, Wu J, Zhou Z, Ma J. Systematic Review and Meta-Analysis of 16 Randomized Controlled Trials of Clinical Outcomes of Low-Intensity Extracorporeal Shock Wave Therapy in Treating Erectile Dysfunction. Am J Mens Health. 2022 Mar-Apr;16(2).
- 40. Yoon SY, Kim YW, Shin IS, Moon HI, Lee SC. Does the Type of Extracorporeal Shock Therapy Influence Treatment Effectiveness in Lateral Epicondylitis? A Systematic Review and Meta-analysis. Clin Orthop Relat Res. 2020 Oct;478(10):2324-2339.
- 41. Zhang L, Fu XB, Chen S, Zhao ZB, Schmitz C, Weng CS. Efficacy and safety of extracorporeal shock wave therapy for acute and chronic soft tissue wounds: A systematic review and meta-analysis. Int Wound J. 2018 Aug;15(4):590-599.
- 42. Zhong Z, Liu B, Liu G, Chen J, Li Y, Chen J, Liu X, Hu Y. A Randomized Controlled Trial on the Effects of Low-Dose Extracorporeal Shockwave Therapy in Patients With Knee Osteoarthritis. Arch Phys Med Rehabil. 2019 Sep;100(9):1695-1702.



AMA CPT Copyright Statement:

All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.