02-54000-20 Original Effective Date: 03/15/04 Reviewed: 04/25/24 Revised: 05/15/24

Subject: Extracorporeal Shock Wave Therapy in the Treatment of Peyronie's Disease

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
<u>Other</u>	<u>References</u>	<u>Updates</u>			

DESCRIPTION:

Peyronie's disease is an acquired inflammatory disease of the <u>tunica albuginea</u> and adjacent erectile tissue of the penis, most commonly affecting men between the ages of 45 and 60 years old. In the acute inflammatory stage, the patient may experience pain during flaccidity and/or during erection or sexual intercourse. The pain usually resolves over several months as the acute inflammation subsides, and the condition evolves to a progressive <u>fibrosis</u> with development of a palpable plaque. The <u>plaque</u> may result in curvature of the penis, erectile dysfunction, or distal flaccidity. In some patients the plaque may resolve and disappear entirely. The etiology of Peyronie's is unknown, but is thought to be related to subclinical trauma.

Patients may seek treatment both for relief of pain during the acute inflammatory phase, and the sexual dysfunction and distortion characterizing the chronic phase. However, conservative treatment options are limited and there is currently no standard non-surgical therapy. There has been interest in extracorporeal shock wave therapy (ESWT) as a treatment of Peyronie's disease and while ESWT is a standard urological therapy to disintegrate kidney stones, the mechanism of action is unknown in Peyronie's disease, where the plaques may or may not be calcified. Similar to its proposed mechanisms of action in other soft tissue conditions it has been proposed that ESWT may prompt increased vascularization and a healing response.

Summary and Analysis of Evidence: An UpToDate review, "Peyronie's disease: Diagnosis and medical management" (Brant, 2023) states, "This modality remains an investigational treatment due to the lack of well-designed trials with long-term follow-up. There are also concerns about the potential side effects, including penile fibrosis, secondary PD scarring, and development of erectile dysfunction." The 2019 Restorative Therapies for Erectile Dysfunction: Position Statement From the Sexual Medicine Society of North America (SMSNA) includes, "A major limitation to most LiSWT studies is the lack of

randomization to a sham control cohort. A number of studies have performed randomization and provided sham controls (ie, identical treatment protocols without shocks) and blinding both patients and providers, whenever possible. Blinding providers is especially important since end-point analysis often included functional surveys like EHS, IIEF, and SHIM. Therefore, clinical trials exploring the types of shockwave, utilization of sham control cohorts, and comparing patient populations would be very helpful in further identifying ideal treatment candidates and true ability to use this restorative therapy for management of ED. Likewise, more studies with variable protocols are needed to find the ideal dosing for maximal effect. Similarly, given the broad spectrum of treatment protocols future clinical trials should attempt to provide some standardization in both device settings (measured in total energy of treatment or EFD) as well as duration of treatment (6 months, 1 year, or greater). This would allow for larger multi-center studies and enable comparison between different trials." Due to the lack of controlled trials, the available published literature is insufficient to permit scientific conclusions regarding the safety and efficacy of ESWT as a treatment of Peyronie's disease.

POSITION STATEMENT:

Extracorporeal shock wave therapy (ESWT) is considered **experimental or investigational** for the treatment of Peyronie's disease. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low
	energy (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 reviewed date.

DEFINITIONS:

Fibrosis: the formation of fibrous tissue.

Plaque: a localized abnormal patch on a body part or surface and especially on the skin.

Tunica albuginea: the dense, white, inelastic tissue immediately covering the testis.

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 04/25/24.

GUIDELINE UPDATE INFORMATION:

03/15/04	New Medical Coverage Guideline.
03/15/05	Scheduled review and revision of guideline consisting of updating references and
	maintaining investigational status.

03/15/06	Annual review; G0280 removed. Continue investigational.
03/15/07	Scheduled review and revision of guideline consisting of updated references.
06/15/07	Reformatted guideline.
02/15/08	Annual review: investigational status maintained, and updated references.
02/15/09	Annual review: investigational status maintained, and updated references.
12/15/09	Annual review: investigational status maintained, and updated references.
05/11/14	Revision: Program Exceptions section updated.
08/15/17	Review; investigational position maintained, description section and references updated.
10/15/19	Review; Position statement maintained and references updated.
06/15/21	Review; Position statement maintained; references updated.
06/15/23	Review: Position statement maintained; references updated.
01/01/24	Annual CPT/HCPCS coding update. Code 0864T added.
05/15/24	Review: Position statement maintained; description and references updated.