Extracorporeal shock wave treatment for chronic tendinitis of the elbow (lateral epicondylitis)

BlueCross BlueShield Association

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

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Citation

Authors' objectives
This Assessment evaluates whether extracorporeal shock wave treatment (ESWT) improves health outcomes for patients with lateral epicondylitis that is unresponsive to conservative treatment. This Assessment updates the 2003 TEC Assessment, which concluded that ESWT did not meet the TEC criteria for treatment of chronic lateral epicondylitis. The purpose of this Assessment is to reassess whether the evidence on ESWT for lateral epicondylitis meets the TEC criteria in light of newly available studies.

Authors' conclusions
Based on the available evidence, the Blue Cross and Blue Shield Medical Advisory Panel made the following judgments about whether ESWT meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria for tendinitis of the elbow (lateral epicondylitis).

1. The technology must have final approval from the appropriate governmental regulatory bodies.

There are currently 3 ESWT devices approved by the U.S. Food and Drug Administration (FDA) via the premarket application (PMA) approval process. The OssaTron device (HealthTronics, Marietta, GA), an electrohydraulic delivery system, was initially approved by the FDA on October 12, 2000, for patients with chronic proximal plantar fasciitis that has failed to respond to conservative management (defined as lasting 6 months or more). The OssaTron was subsequently approved via a supplemental PMA on March 14, 2003, for the treatment of chronic lateral epicondylitis that has failed to respond to conservative treatment (defined as lateral epicondylitis that has persisted for 6 months or more with a history of unsuccessful conservative treatment). The Dornier Epos Ultra (Dornier Medical Systems, Inc.; Kennesaw, GA), an electromagnetic delivery system, was approved on January 15, 2002, for the treatment of chronic plantar fasciitis for patients with symptoms of plantar fasciitis for 6 months or more and a history of unsuccessful conservative therapy. The SONOCUR Basic (Siemens Medical Solutions, USA; Iselin, NJ) also uses an electromagnetic delivery system and was approved for chronic lateral epicondylitis (defined as lasting 6 months or more and with a history of unsuccessful conservative treatments) on July 19, 2002.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

Six trials evaluated ESWT for tendinitis of the elbow. All were randomized, double-blind, placebo-controlled trials. The SONOCUR FDA data (n=114) reported statistically significant improvement in pain on resisted extension and the upper extremity function score. The OssaTron FDA data (n=183) reported statistically significant improvement in investigator assessment of pain, but were not significant for patient assessment of pain and non-use of pain medication. The Speed et al. study (n=75) reported no group differences on elbow pain during the day or at night. This study appeared to have some group differences at baseline; although none was reported as statistically significant. The Haake et al. study (n=272) found no difference between ESWT and placebo. The Melikyan et al. study (n=74) reported no
group differences. This study did not conduct an intent-to-treat analysis to account for dropouts. The Rompe et al. study (n=78) reported statistically significant improvement in pain on resisted extension, the Roles and Maudsley score, the Upper Extremity Function score, and satisfaction with return to activities. Overall, the available data does not provide strong and consistent evidence that ESWT improves outcomes of chronic lateral epicondylitis. Thus, the second TEC criterion is not met.

3. The technology must improve the net health outcome.

The evidence is not sufficient to permit conclusions on the health outcome effects of ESWT for chronic lateral epicondylitis; therefore, it is not possible to conclude whether overall health outcomes are improved.

4. The technology must be as beneficial as any established alternatives.

The evidence is not sufficient to permit conclusions on the health outcome effects of ESWT for chronic lateral epicondylitis; therefore, it is not possible to conclude whether the technology is as beneficial as alternatives.

5. The improvement must be attainable outside the investigational settings.

Whether ESWT for chronic lateral epicondylitis improves health outcomes has not been demonstrated in the investigational setting.

Therefore, based on the above, extracorporeal shock wave treatment for chronic lateral epicondylitis does not meet the TEC criteria.