Washington State Health Care Authority, HTA Program
Bone Growth Stimulators
Final Key Questions and Background

Introduction

HTA has selected Bone Growth Stimulators to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input about available evidence. HTA published the draft key questions, and considered all public comment input and any additional evidence submitted prior to finalizing the key questions. Key questions guide the development of the draft evidence report.

Bone Growth Stimulation is a technique of promoting bone growth in difficult to heal fractures or in areas trying to be fused by applying a low electrical current or ultrasound to the fracture.

Final Key Questions

1. What is the evidence of efficacy and effectiveness (accelerated healing, bone fusion, reduced pain, improved functional status) of bone stimulators (ultrasound, invasive, and non-invasive) compared to treatment without stimulators:
    a. When used to treat persons with delayed or nonunion fractures of
        i. Long bones
        ii. Bones of wrist?
        iii. Other bones?
    b. When used to treat subgroups with comorbidities that may increase risk of fracture non-union with fresh fractures of
        i. Long bones
        ii. Bones of wrist?
        iii. Other bones?
    c. When used to treat failed fusion of spinal vertebrae (lumbar and cervical) or in patients at risk of failed fusion due to comorbidities?

2. What is the evidence about the safety profile?

3. What is the evidence of cost implications and cost effectiveness?

Technology Background

Technology: Bone Growth Stimulation is a technique of promoting bone growth in difficult to heal fractures or in areas trying to be fused by applying a low electrical current or ultrasound to the fracture. Fully implantable direct current stimulators are installed in a hospital under general or regional anesthesia. Both the stimulator and the power source are implanted. The surgeon makes an incision and places a spiral shaped cathode inside the bone. A wire leads to the power source and a small anode. The power source is a battery pack that is implanted in the nearby muscle. Partially implanted stimulators are cathode pins that are implanted at the edge of each bone that is fractured. Wires lead to the surface of the skin where a power source and the anode are located. Wires complete the circuit. The external portion of the device is held in place by a cast. This source of stimulation also runs continuously. Ultrasound stimulation is a device that generates low intensity pulses of sound and is applied to the skin over the fracture. Each method (electrical and ultrasound) must be used for at least three to six months to be effective. Questions about the effectiveness and durability of the treatment remain, as well as safety questions related especially to implanted techniques that carry attendant surgical risks.