NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Exogen Ultrasound Bone Healing System

Date:	December 2020	Date of Next Review:	December 2022

Following a review of the evidence and consideration of the local circumstances for use, Cambridgeshire and Peterborough Clinical Commissioning Group will separately fund (in accordance with this policy and NICE MTG published January 2013 and updated October 2019 to reflect 2019 costs.

- **use of Exogen® ultrasound bone healing system to treat long bone fractures with non-union, in accordance with defined clinical and process criteria**

Cambridgeshire and Peterborough Clinical Commissioning Group will not separately fund:

- **use of Exogen® ultrasound bone healing system to treat long bone fractures with delayed union**
- **any other indications for use of Exogen® ultrasound bone healing system**

Definition:

The Exogen® ultrasound bone healing system delivers low-intensity pulsed ultrasound waves with the aim of stimulating bone healing. It is thought that healing is promoted by stimulating the production of growth factors and proteins that increase the removal of old bone, increase the production of new bone and increase the rate at which fibrous matrix at a fracture site is converted to mineralised bone.

Long bone fractures are suitable for treatment if the fracture is stable and well aligned. Exogen® is not indicated for use in fractures of the skull or vertebrae or in children or adolescents because of their skeletal immaturity.

The Exogen® system is a single hand-held device with 2 treatment options: Exogen®150 and Exogen® 250. These are equivalent to the former versions Exogen® Express and Exogen® 4000+ respectively. The device has a visual treatment-tracking calendar and treatment history log aimed at improving compliance. Exogen® controls the number of treatments performed using an SD card. The device operates on a low lithium battery and has a battery door and charger. The device also has a smartphone app, Exogen® Connects, which enables adherence by providing information such as treatment reminders, information on fracture healing and videos on how to use Exogen®. The phone app has not been assessed as part of the evaluation.

The Exogen® device consists of a main operating unit with a permanently connected transducer and a separate fixture strap. The strap is placed around the fractured bone, coupling gel is applied to the transducer head (to aid conduction of ultrasound) and the transducer is secured directly over the fracture site by a fixture on the strap. The ultrasound signal emitted by the device is derived from a combination of defined electrical signal parameters and the proprietary transducer design, which generate an acoustic wave pattern specific to Exogen®. If the patient's limb is immobilised in a cast then a hole is cut in the cast to allow access of the transducer to the skin. The device is programmed to deliver ultrasound in 20 minute sessions and these are self-administered by the patient each day. It is intended to be used in the patient's home.

Evidence and rationale:

The NICE review in 2013 of Exogen® when used for long-bone fracture with non-union was from observational studies with limited outcomes but with good clinical results, with healing rates ranging from 75% to 100% (depending on the long bone involved and duration of non-healing) over a period of 4.6 to 7.3 months and hence the reason for support from NICE.

The evidence for use of Exogen® when used for long bone fracture and delayed healing is more limited and the outcomes varied. In addition there are uncertainties about the rate at which healing progresses between 3 and 9 months after fracture, both with and without Exogen®, and about whether surgery would be required if Exogen® were not used. Some of the delayed healing studies include a significant number of patients (50%) considered to be non-union, with no sub-group analysis.

The evidence was not assessed for other indications associated with the use of Exogen® ultrasound bone healing system.

NICE IPG623 published in July 2018 found the evidence for low-intensity pulsed ultrasound (LIPUS) to promote healing of delayed-union and non-union fractures (across all types of fractures) raises no major safety concerns. The current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

The NICE guidance evidence update for Exogen® in 2019 identified 3 systematic reviews (of limited benefit for this review) and 5 observational studies reporting healing rates for long bone non-union fractures ranging from 32.8% to 88% (depending on the long bone involved and the duration of non-healing). Data from 3 relevant NHS audits showed a healing rate ranging from 39 to 72%.

Overall the additional clinical evidence identified since the guidance was published in 2013 supports the current recommendations.

Adverse events associated with use of Exogen® appear to be minimal, with 3 cases of skin irritation (from the coupling gel) and 1 report of chest pain (associated with a cardiac pacemaker) during a 1 year period of use reported on a database operated by the FDA and MAUDE (Manufacturer and User facility Device Experience). The manufacturer's suggested that 55,000 devices were used during this time period.

- None of the clinical studies reported device-related events and no safety concerns were identified by the external assessment centre in relation to Exogen®.
- Reports on surgical treatment of non-union and delayed healing fractures documented adverse events including postoperative wound infection, osteomyelitis and pain.

Risks:

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REFERENCES:

NICE: Exogen® ultrasound bone healing system for long bone fractures with non- union or delayed healing. Medical Technology Guidance 12. January 2013. https://www.nice.org.uk/guidance/mtg12/resources/exogen-ultrasound-bone-healing-system-for-long-bone-fractures-with-nonunion-or-delayed-healing-pdf-64371871020229

NICE: Review of Medical Technology Guidance 12. Review Decision October 2019. https://www.nice.org.uk/guidance/mtg12/chapter/1-recommendations

NICE: Low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures. Interventional Procedures Guidance 623. July 2018. https://www.nice.org.uk/guidance/IPG623