

DRAFT

**Policy for the use of EXOGEN
ultrasound bone healing
system**

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Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
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Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Not Routinely Commissioned

Fracture

Following immediate management of a presenting fracture through casting, traction or surgical intervention, patients receive regular follow-up to determine progression of healing. In children and adolescents healing rates in the order of 99% are usual, whilst in adults this is around 80% depending on the bone involved.

Healing of fractures varies according to the nature of the fracture and affected bone, host factors including age, co-morbidities and lifestyle factors and other issues such as surgical aspects and infection. The definition of non-union therefore can vary according to these parameters. It is usual practice to consider non-union from around 6 months following fracture; at this stage re-intervention is considered.

Long bone fractures are usually treated immediately by closed or open reduction realignment of the bone ends, which can involve surgery). The affected limb is immobilised using a cast or by internal or external fixation. X-rays are used to verify alignment of the bone. Progress towards fracture healing is usually assessed by X-ray demonstration of bridging of the gap between the fractured bone ends with new bone cortex.

Patients with delayed fracture healing at 3 months do not usually have surgery at this time unless the fracture is complex (for example, an unstable or misaligned fracture or an inter-fragment gap of more than 10 mm). Surgery may take place between 3 and 9 months after fracture, but clinical practice varies and decisions about the timing of surgery are made on an individual patient basis. If surgery is considered necessary, it usually involves internal or external fixation and bone grafting (with harvesting from the patient's iliac crest).

Exogen Ultrasound Bone Healing System

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 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 Review

The evidence reviewed was mixed, whilst NICE supported this treatment intervention in certain clinical circumstances, there was acknowledgement from the NICE Committee (MTG12) that for long bone fractures with delayed healing the Committee considered that the clinical evidence was more limited. In addition, there were significant uncertainties about the rate at which healing progresses between 3 and 9 months after fracture, both with and without EXOGEN, and about whether or not surgery would be required if EXOGEN was not used. These and other considerations influenced the Committee's views about the most appropriate assumptions for cost modelling: the model considered to be most appropriate estimated that EXOGEN treatment would be more costly than current management. The Committee therefore judged that the case for adoption of EXOGEN to treat long bone fractures with delayed healing was not supported by the current evidence.

Therefore, due to the lack of consistent evidence and in light of the uncertain cost benefits of this treatment in preventing surgery, exogen bone healing will not be routinely commissioned.

N.B. It is understood that NICE are due to published revised guidelines (MTG12 - exogen bone healing system), which if published in time, will be taken into consideration by the committee as part of the public engagement in Sept – October 2019.

Eligibility Criteria

The use of Exogen ultrasound bone healing system is Not Routinely Commissioned due to a lack of robust clinical evidence to support this intervention.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

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Guidance

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11. [3] Healing of fracture nonunions treated with low-intensity pulsed ultrasound (LIPUS): A systematic review and meta-analysis (2017) - <https://www.sciencedirect.com/science/article/pii/S0020138317303418>
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