

16. Exogen Ultrasound Bone Healing Commissioning Statement

Treatment	Exogen® Ultrasound Bone Healing
Background	<p>From April 2013, NHS England took over responsibility for commissioning activity in primary care, where initial conservative treatment takes place. NHS Vale of York CCG is responsible for commissioning activity in secondary care.</p> <p>The Exogen® ultrasound bone healing system delivers ultrasound waves with the aim of stimulating bone healing. Long bone fractures with non-union (most commonly tibia) are suitable for treatment if the fracture is stable and well aligned. Tibial fractures also appear to have the best healing rates and outcomes. Exogen® is not indicated for use in fractures of the skull or vertebrae or in children or adolescents because of their skeletal immaturity.</p>
Commissioning position	<p>This commissioning policy is needed to provide a commissioning position for the use of Exogen.</p> <p>The use of the Exogen® system to treat long bone fractures with delayed union or any other indications is NOT commissioned.</p> <p>(NB: NHS Vale of York CCG does NOT routinely commission an elective intervention on patients who have a BMI of 30 or above (classified as obese) or patients who are recorded as a current smoker – see commissioning statement 01. Optimising Outcomes from All Elective Surgery**)</p> <p>NHS Vale of York Clinical Commissioning Group will fund the use of the Exogen® system to treat long bone fractures with non-union, in accordance with defined clinical criteria as follows:</p> <ul style="list-style-type: none"> • Patient age > 18 years • Non-union of fracture > 9 months • Not to be used in cases of unstable surgical fixation, not well aligned or where inter-fragment gap is > 10mm • Not to be used in cases with infection • Not to be used in pregnancy, patients with pacemakers or vertebral/skull fractures • Only when lifestyle factors addressed** <p>**Note: patients with lifestyle factors which are known to delay fracture healing rates e.g. smoking and excess alcohol intake (i.e. men and women should not drink more than <u>14 units</u> of alcohol each week¹), will be appropriately counselled and required to eliminate these risks before determining non-union status and ultimately eligibility for Exogen®. Where appropriate, referrals to specific support services should be arranged e.g. smoking cessation service.</p> <p>NHS Vale of York Clinical Commissioning Group will NOT fund the use of the Exogen® system to treat long bone fractures with delayed union or any other indications for use of Exogen®.</p> <p>These criteria will be reviewed on publication of new evidence in the form of relevant trial data, updated national guidance, or national or local audit outcomes.</p>

	<p>Any identified new indications for use of the Exogen® system requiring additional funding will only be considered in exceptional circumstances through the Individual Funding Request Panel.</p>
<p>Summary of evidence / rationale</p>	<p>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 and the transducer is secured directly over the fracture site. The transducer generates an acoustic wave pattern specific to Exogen®. If the patient's limb is immobilised in a cast then a hole is cut to allow access to the skin. 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 bone².</p> <p>The device is programmed to deliver ultrasound in 20-minute sessions and these are self-administered by the patient each day, generally over several months. It is intended to be used in the patient's home. The only type of device shown to be cost-effective in treating non-union (one can deliver more than 6 months' treatment) is the Exogen 4000+, cost around £2500 (price 2013; excludes VAT)².</p> <p>NICE published guidance for Exogen® in January 2013². This states that the technique is cost-saving over traditional surgery when used for treatment of long bone fractures with non-union.</p> <p>The NICE MTG states that:</p> <ul style="list-style-type: none"> • The case for adopting the Exogen® system to treat long bone fractures with non-union (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing. • About one third of non-union tibial fractures might be suitable for treatment with Exogen and thereby avoid surgery • The Exogen® 4000+ system to treat long bone fractures with non-union is associated with an estimated cost saving of £1164 per patient compared with current management, through avoiding surgery. (Note: this level of cost-saving has not been established locally) • There is some radiological evidence of improved healing when the Exogen® system is used for long bone fractures with delayed healing (no evidence of healing after about 3 months). There are substantial uncertainties, however, about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery would still be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management. <p>It should be noted that all the evidence associated with Exogen® when used for long-bone fracture with non-union is 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. This is the reason for support from NICE.</p> <p>Comparative evidence with surgery is limited. Healing rates from surgical intervention as identified in case series/cohort studies range from 62 to 100% over a period of 9 to 24 weeks.</p>

	<p>The evidence for use of Exogen® when used for long bone fracture and delayed healing is more limited and the outcomes varied. Uncertainties about the rate at which healing progresses after fracture, both with and without Exogen®, and about whether surgery would still be required, are outlined in the MTG as mentioned above. This therefore raises many uncertainties about the cost savings. . Some of the delayed healing studies include a significant number of patients (50%) considered to be non-union, with no sub-group analysis.</p> <p>Adverse events associated with use of Exogen® appear to be minimal. None of the clinical studies reported device-related events and no safety concerns were identified by the external assessment centre in relation to Exogen®.</p> <p>Reports on surgical treatment of non-union and delayed healing fractures documented adverse events including postoperative wound infection, osteomyelitis and pain.</p>
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Author	Dr Alison Forrester, Healthcare Public Health Advisor CYC & NYCC
Approved by	Clinical Research & Effectiveness Committee 22.11.16
Responsible officer	Dr Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net

Reference:

1. New alcohol guidelines show increased risk of cancer. Department of Health: Updated alcohol consumption guidelines give new advice on limits for men and pregnant women. 8 January 2016.
<https://www.gov.uk/government/news/new-alcohol-guidelines-show-increased-risk-of-cancer>
2. 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>