

Exogen[®] Ultrasound Bone Healing System for Bone Fractures with Non-Union

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CONSULTATION SCHEDULE		
<u>Name and Title of Individual</u>	<u>Groups consulted</u>	<u>Date Consulted</u>
Dr John Harvey	Consultant in PH	Jan 2018

APPROVALS & RATIFICATION SCHEDULE	
Name of Committee approving Policy	Date
Planning and Commissioning Committee (N.S & SOT CCGS)	20.02.2018
South West Membership Meeting in common	08.06.2022
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Integrated Care Board	01.07 2022

VERSION CONTROL			
V	Version/Description of amendments	Date	Author/amended by
1	New Policy	20.02.20	Kathryn Whitfield
2	Adopted by SSOT ICB	01.07.20	Jane Chapman

Impact Assessments – available on request			
	Stage	Complete	Comments
Equality Impact Assessment			
Quality Impact Assessment			
Privacy Impact Assessment			

1 Policy statement:

Following a review of the evidence and consideration of the local circumstances for use, the Staffordshire & Stoke-on-Trent Integrated Care Board will fund (in accordance with this policy):

1.1 Exogen[®] ultrasound bone healing system **for the treatment of** bone fractures with non-union, in accordance with defined clinical and process criteria

2 Scope of policy:

2.1 This policy should be considered in line with all other Staffordshire and Stoke on Trent ICB Commissioning Policies. Copies of these Commissioning Policies are available on the ICB's websites

2.2 This policy relates to the use of Exogen[®] ultrasound bone healing system when used for management of bone fractures which are subject to **non-union**, in an out-patient setting

3 Background

3.1 NHS principles have been applied in the agreement of this policy.

3.2 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

3.3 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 or 3 months for fracture neck of femur in some cases, at this stage re-intervention is considered. However nearly all fractures heal within 3-4 months¹. The difference between delayed healing and non-union is arbitrary and radiological evidence of a persistent fracture line is designated as delayed healing or non-union. However there are differing clinical observations in the different stages of delayed healing which can be seen in the table below²

Table 1: Frequent observations in patients with different stages of impaired fracture healing

	Delayed Union	Non-union	Pseud arthrosis
Symptoms	Painful	Painful	No pain
Radiograph	Hypertrophic	Hypertrophic or	Hypertrophic or atrophic
Healing	Spontaneous healing	No spontaneous	Only surgical treatment

Source: reference 2 below

3.4 Exogen[®] has been available since 1997 and since this time has been assessed in the form of observational studies. In January 2013, the National Institute for Health and Clinical Excellence

¹ Frolke, JPM and Patka, P (2007) 'Definition and classification of fracture non-unions', Injury, Internal Journal Care Injured. www.elsevier.com

² Frolke, JPM and Patka, P (2007) 'Definition and classification of fracture non-unions', Injury, Internal Journal Care Injured. www.elsevier.com

(NICE 2013) completed a review of the technology and the associated evidence for use. The outcomes of this review were published as Medical Technology Guidance 12

3.5 NICE medical technologies guidance helps the NHS to adopt medical technologies more rapidly and consistently by advising on efficacy and cost effectiveness. NICE has not issued a mandatory requirement to fund this intervention

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

3.6 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

3.7 The EXOGEN[®] system is available as 2 disposable devices, which differ only in the number of treatments they deliver:

- The EXOGEN[®] 4000+ is intended for use in patients with non-union fractures (fractures that have failed to heal after 9 months). The device delivers a minimum of 191x20 minute treatments (more than 6 months' treatment).
- The EXOGEN[®] Express is intended for use in patients with delayed healing fractures (fractures that have no radiological evidence of healing after 3 months). The device delivers a maximum of 150x20 minute treatments (less than 5 months' treatment). (**NB:** EXOGEN[®] 4000+ will only be funded under this policy)

3.8 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

4 Relevant National Guidance and Research

4.1 NICE published Medical Technology Guidance (MTG12) for Exogen[®] in January 2013. This demonstrates that this ultrasound technique is cost-saving over traditional surgery when used for treatment of long bone fractures with non-union. The NICE recommendations are:

- The case for adopting the EXOGEN[®] ultrasound bone healing 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

- The EXOGEN® ultrasound bone healing system to treat long bone fractures with non-union is associated with an estimated provider cost saving of £1164 per patient compared with current management, through avoiding theatre time and bed days saved for NHS Trusts. (Note: this level of cost-saving has not been established locally)
- There is some radiological evidence of improved healing when the EXOGEN® ultrasound bone healing system is used for long bone fractures with delayed healing (no radiological evidence of healing after approximately 3 months). There are substantial uncertainties 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 be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management

4.2 NICE estimates assume the following:

- 21.4% of fractures are non-union after 9 months
- Around 50% of non-unions are not suitable for Exogen® therapy

5 Evidence for Use

5.1 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 and hence the reason for support from NICE.

- A small study suggests that where Exogen® is used in patients with non-union > 12 months, much lower healing rates are observed e.g. 65%
- Although limited, the evidence also suggests different healing rates associated with differing long- bones, with the tibia appearing to have the best outcomes (some reports of 100%); this is also the bone which most commonly fractures and for which non-union most commonly occurs. This evidence was supported by the views of clinical experts involved in the NICE MTG
- 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 weeks to 24 weeks
- Different trials used different definitions for non-union including: failure of fracture to unite at a minimum of 6 months from fracture, no progression towards radiographic healing or healing had stopped for a minimum period of 3 months before Exogen®. The largest trial (256 patients) used the definition of 9 months from fracture

5.2 The evidence has not been assessed for other indications associated with use of Exogen® ultrasound bone healing system and these would be outside the scope of this policy

5.4 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 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

6 Commissioning Policy

NHS Staffordshire and Stoke-on-Trent ICB, (termed “the Commissioners”) consider all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to the patient’s clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

6.1 Use of Exogen® for bone fractures with non-union

Exogen® will be funded where **all** the following **criteria** are met:

6.1.1 Clinical

- Patient age > 18 years
- Non-union of **any bone** fracture > 9 months and < 12 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
- Note: patients with lifestyle factors which are known to delay fracture healing rates e.g. smoking and excess alcohol intake, 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

6.1.2 Process

- Patient ability to comply with usage protocol and criteria
- Patients to be screened and referred by Consultant Orthopaedic Surgeon following review on at least two occasions at least 4 weeks apart to allow examination of serial x-rays
- Further assessment in non-union clinic by surgeon with expertise of dealing with non-union of bones
- Regular audit of outcomes to be undertaken and participation in regional network where available

These criteria will be reviewed and updated on publication of new evidence in the form of relevant trial data, updated national guidance or national or local audit outcomes.

6.2 Reporting requirements and funding arrangements are detailed in Appendix 1

- Use of Exogen® for any bone fracture with delayed healing. Exogen® will not be funded for use in this indication
- Other indications for use of Exogen®
- No other indications for use of Exogen® ultrasound bone healing system without these indications will be funded
- Any identified new indications for use require submission of a new technology request form for consideration to the Clinical Priorities Advisory Group (CPAG)

7 Clinically Exceptional Circumstances

7.1 If there is demonstrable evidence of a patient's clinical exceptional circumstances, the referring practitioner should refer to the Commissioner's Operational Policy for Individual Funding Requests(IFR) document for further guidance on the process for consideration.

8 Appendix 1: Reporting Requirements and Funding Arrangements

Commissioner funded Exogen® Ultrasound Bone Healing System for Any Bone Fractures with Non-union

1. Funding Arrangements

1.1 For treatment failures where there is continued non-union of the any bone fracture after six months of Exogen therapy providers will need to recover costs via the manufacturers “money back guarantee” arrangement (see appendix 2). This will then need to be credited back to the commissioners

Additional points to note:

- Local intelligence suggests that activity levels for each Trust will be <10 per annum, should this increase the ICB will review to monitor financial risk

2. Reporting Requirements – All Approved Indications

The information detailed in the table below should be provided to commissioners every 6 months. The preferred route for submission of data is via Blue Teq or via the CSU in the absence of the Blue Teq system within the Trust.

Table 1: Information requirements for the use of Exogen therapy in long bone non-union of fractures

Date initiated	Purchaser Code	Hospital Site	Pseudonymised Patient Number	Duration Non-healing	Stability Y/N	Type or location of fracture	Alternative treatment procedure code	Treatment Success/Failure S/F	Date of final assessment	Time to heal/failure (weeks)	Refunded for failure Y/N	Cost Exogen® claimed

9 Appendix 2: Exogen – Performance Guarantee

PERFORMANCE GUARANTEE

The EXOGEN Performance Guarantee is a Bioventus program that refunds to buyers participating in the program, the payment for EXOGEN if progression of healing (progression to bony union)

is not shown per criteria below. It is also designed to help reinforce patients' adherence for the prescribed treatment.

Criteria

Buyers of EXOGEN participating in the program are eligible when the device has been prescribed by a qualified physician to treat a stable, established non-union[†] fracture with a fracture gap less than 10 millimetres (excluding vertebra and skull fractures).

Patients must treat their non-union fracture with EXOGEN per product instructions, for a minimum of 120 days and achieve a 90% minimum adherence.

Evaluation

Absence of healing (progression to bony union e.g. callus formation) is determined by the prescribing physician comparing the patient's X-Rays taken prior to using EXOGEN to one taken at 120 days or beyond.

The EXOGEN device contains an internal patient usage monitor that records the date, time and duration of each treatment.

This monitor will be used by Bioventus to confirm that the 90% treatment adherence is met.

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Exclusions

- Fracture types:
 - Fresh fractures
 - Unstable
 - Greater than 10 millimetres fracture gap
 - Vertebra and skull
 - Pathological
- Treatment of multiple fractures (the guarantee is only valid to treat a defined fracture)
- Modified and/or altered devices
- Guarantee is void if alternative interventions occur during the 120 day treatment period
- EXOGEN must be purchased and received directly from Bioventus
- Any other costs associated with the purchase (only the cost of the EXOGEN device will be refunded)
- Valid only in UK and Ireland

Claims

Customers may contact a Bioventus Customer Care Representative at 0800 05 16 384 (UK) or 1800 552 197 (Ireland)

for assistance. All claims must be accompanied by the following:

1. Registration form to the Performance Guarantee Program sent to Bioventus within the first 30 days of the initial treatment.
 2. Prescribing physician's written assessment, using the EXOGEN Claim Form
 3. Prescribed EXOGEN device returned to Bioventus
- Claims must be received by Bioventus within one year of first EXOGEN treatment date.

Summary of Indications for Use

EXOGEN is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) that includes the treatment of delayed unions, non-unions[†], stress fractures and joint fusion. EXOGEN is also indicated for the acceleration of fresh fracture heal time, repair following osteotomy, repair in bone transport procedures and repair in distraction osteogenesis procedures.

[†]A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

There are no known contraindications for the EXOGEN device. Safety and effectiveness have not been established for individuals lacking skeletal maturity, pregnant or nursing women, patients with cardiac pacemakers, on fractures due to bone cancer, or on patients with poor blood circulation or clotting problems. Some patients may be sensitive to the ultrasound gel.

Full prescribing information can be found in product labelling, at www.exogen.com.

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