

**Commissioning Policy**

**Exogen<sup>®</sup> Ultrasound Bone Healing System  
 for Long Bone Fractures  
 with Non-Union or Delayed Healing**

**September 2014**

**This commissioning policy has been endorsed by and applies to patients within:**  
 NHS South Worcestershire Clinical Commissioning Group (CCG)  
 NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)  
 NHS Wyre Forest Clinical Commissioning Group (CCG)

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<b>Expiry date: (Document is not valid after this date)</b>	Any revisions to the policy will be based on local and national evidence of effectiveness and cost effectiveness together with recommendations and guidelines from local, national and international clinical professional bodies.  Minimum 3 yearly.
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### Review and Amendment Log

Version No	Type of Change	Date	Description of change
1.0	Initial Policy	04/09/2014	Policy development

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## **SUMMARY**

Following a review of the evidence and consideration of the local circumstances for use, Worcestershire Clinical Commissioning Groups **will separately fund** (in accordance with this policy):

- use of Exogen<sup>®</sup> ultrasound bone healing system to treat long bone fractures with non-union, in accordance with defined clinical and process criteria (see page 7)

Worcestershire Clinical Commissioning Groups **will not separately fund**:

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

Any identified new indications for use of Exogen<sup>®</sup> ultrasound bone healing system requiring additional funding will require submission of a new technology request form for consideration by Worcestershire Clinical Commissioning Policy Collaborative.

## **1. Definitions**

- 1.1 Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.
- 1.2 A Similar Patient** refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Primary Care Trust collaborates. The existence of one or more similar patients indicates that a policy position is required of the Primary Care Trust.
- 1.3 An individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.
- 1.4 An in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Primary Care Trust agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

## 2. Scope of policy:

- 2.1 This policy should be considered in line with all other Worcestershire Commissioning Policies. Copies of these Commissioning Policies are available on the following website address:  
<http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/>
- 2.2 This policy relates to use of Exogen<sup>®</sup> ultrasound bone healing system when used for management of long bone fractures in an out-patient setting.
- 2.3 The Exogen<sup>®</sup> 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.
- 2.4 Long bone fractures are suitable for treatment if the fracture is stable and well aligned. EXOGEN<sup>®</sup> is not indicated for use in fractures of the skull or vertebrae or in children or adolescents because of their skeletal immaturity.
- 2.5 The EXOGEN<sup>®</sup> system is available as 2 disposable devices, which differ only in the number of treatments they deliver:
- The EXOGEN<sup>®</sup> 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<sup>®</sup> 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).
- 2.6 The EXOGEN<sup>®</sup> 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<sup>®</sup>. 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.

## 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; at this stage re-intervention is considered.
- 3.4. Exogen<sup>®</sup> 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 (NICE) 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.

## 4. Relevant National Guidance and Facts

- 4.1. NICE published Medical Technology Guidance (MTG12) for Exogen<sup>®</sup> 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:
  - 4.1.1. The case for adopting the EXOGEN<sup>®</sup> 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.
  - 4.1.2. The EXOGEN<sup>®</sup> ultrasound bone healing 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)*
  - 4.1.3. There is some radiological evidence of improved healing when the EXOGEN<sup>®</sup> 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% (and locally up to 70%) of non-unions are not suitable for Exogen therapy
  - 82% of patients do not heal after either 6 months following surgery or 6 months following Exogen<sup>®</sup>, thus resulting in the same failure rate of 18%.

## 5. Evidence for Use

- 5.1 It should be noted that all the evidence associated with Exogen<sup>®</sup> 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<sup>®</sup> is used in patients with non-union > 12 months, much lower healing rates are observed eg. 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<sup>®</sup>. The largest trial (256 patients) used the definition of 9 months from fracture.
- 5.2 The evidence for use of Exogen<sup>®</sup> 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<sup>®</sup>, and about whether surgery would be required if Exogen<sup>®</sup> 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.
- 5.3 The evidence has not been assessed for other indications associated with use of Exogen<sup>®</sup> ultrasound bone healing system.
- 5.4 Adverse events associated with use of Exogen<sup>®</sup> 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<sup>®</sup>.
  - Reports on surgical treatment of non-union and delayed healing fractures documented adverse events including postoperative wound infection, osteomyelitis and pain.

## **6. Commissioning Policy**

- 6.1 NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (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.

## 6.2 Use of Exogen<sup>®</sup> for long bone fractures with non-union

Exogen<sup>®</sup> will be funded where the following criteria are met:

### a. Clinical

- Patient age > 18 years
- Non-union of fracture > 6 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 eg. 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<sup>®</sup>. Where appropriate, referrals to specific support services should be arranged eg. smoking cessation service.

### b. 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 long bones; Appropriateness of Exogen<sup>®</sup> to be determined through agreement of 2 Specialist non-union Consultants.
- Regular audit of outcomes to be undertaken and participation in regional network where available.

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

Reporting requirements and funding arrangements are detailed in Appendix 1.

## 6.3 Use of Exogen<sup>®</sup> for long bone fracture with delayed healing

Exogen<sup>®</sup> will not be funded for use in this indication.

## 6.4 Other indications for use of Exogen<sup>®</sup>:

No other indications for use of Exogen<sup>®</sup> ultrasound bone healing system outwith these indications will be funded.

Any identified new indications for use require submission of a new technology request form for consideration by the Clinical Commissioning Policy Collaboration.

## 7. Clinically Exceptional Circumstances

- 7.1 If there is demonstrable evidence of a patient's clinically exceptional circumstances, the referring practitioner should refer to the Commissioner's "Operational Policy for

Individual Funding Requests” document for further guidance on the process for consideration.

For a definition of the term “clinically exceptional circumstances”, please refer to the **Definitions** section of this document.

## **8. References**

- NICE: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. Medical Technology Guidance 12. January 2013.

## **9. Documents Which Have Informed This Policy**

- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- West Midlands Strategic Group Commissioning Policy 1: Guiding principles and considerations to underpin priority setting and resource allocation within collaborative commissioning arrangements
- West Midlands Strategic Group Commissioning Policy 4: Use of cost-effectiveness, value for money and cost effectiveness thresholds
- West Midlands Strategic Group Commissioning Policy 16: Prior Approval
- West Midlands Strategic Group Commissioning Policy 9: Individual funding requests

**Reporting Requirements and Funding Arrangements**

**Commissioner funded Exogen<sup>®</sup> Ultrasound Bone Healing System for Long Bone Fractures with Non-union**

**1. Reporting Requirements – All Approved Indications**

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

This information should be provided quarterly to the Worcestershire Joint Information Group for validation purposes and will assist with audit of outcomes. Without this level of data Commissioners will be unable to authorise charges for Exogen<sup>®</sup>. It is possible that during 2014/15, a system (BlueTeq) for ensuring compliance of use for new technologies is introduced to the acute trust; it is expected that this would incorporate Exogen<sup>®</sup> at an early stage.

**2. Funding Arrangements**

Exogen<sup>®</sup> will be funded for patients meeting the clinical criteria listed in section 6.2. For treatment failures, providers will ensure that a reimbursement is obtained in accordance with the manufacturers “money back guarantee” arrangement; commissioners will not fund these patients.

The funding of Exogen<sup>®</sup> will be made available at the end of treatment when the outcomes in terms of success or failure are known. A log of users will be kept which will be utilised for invoicing purposes and includes a log of failures and refunds obtained. This system will no longer be necessary once the BlueTeq system is introduced and used for appropriate patients.

**Additional points to note:**

- The Provider will notify the Commissioner if expenditure forecasts suggest expenditure to be >10% of planned levels; investigating these to reduce CCG financial risk.
- Audit of use during 2014/15 will inform the funding arrangements for 2015/16.

## Equality Impact Assessment

Organisation

Department  Name of lead person

Piece of work being assessed

Aims of this piece of work

Date of EIA  Other partners/stakeholders involved

Who will be affected by this piece of work?

Single Equality Scheme Strand	Baseline data and research on the population that this piece of work will affect. What is available? Eg population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. <b>Include consultation with service users wherever possible</b>	Is there likely to be a differential impact? Yes, no, unknown
<b>Gender</b>	There is no correlation between gender and nonunion or delayed union of fractures, although problems in healing are more common amongst males since they have a higher incidence of high energy fractures.	No
<b>Race</b>	Cardiovascular-related illnesses are more prevalent in men from the Indian subcontinent. Peripheral vascular disease adversely affects the blood flow to the tissues, including the bone and the surrounding soft-tissue envelope; this will impair delivery of oxygen, inflammatory cells and nutrients to the fracture site and may affect bone healing rates.	Yes
<b>Disability</b>	Diabetes is more prevalent in black and minority ethnic people. Clinical studies have demonstrated a significantly higher incidence of delayed union, non-union, and a doubling of the time to healing of the fracture in diabetic compared with non-diabetic patients. There could be issues in a patient's ability to operate this device if they have physical disabilities.	Yes
<b>Religion/ belief</b>	No issues	No
<b>Sexual orientation</b>	LGBT people are more likely to smoke and therefore healing rates may be affected.	Yes
<b>Age</b>	The safety and effectiveness of Exogen has not been established in patients with skeletal immaturity ie. children and adolescents. Children and adolescents have much higher healing rates (around 99%) and are unlikely to require this intervention. While the majority of patients being treated for fractures are unlikely to have a nutritional deficiency, a significant minority, particularly in the elderly with fragility fractures may have. Overall, there is some evidence that increasing age is a factor in the inhibition of fracture repair in the human. In addition to the slowing in the process of repair, many problems are encountered in the elderly as a result of difficulties in maintaining fixation of weak, osteoporotic bony fragments for sufficient time for union to occur.	Yes
<b>Social</b>	<b>Malnutrition</b> Nutritional and metabolic requirements increase during fracture repair.	Yes

<b>deprivation</b>	<b>Smoking</b> has been shown to adversely affect bone mineral density, lumbar disc disease, the rate of hip fracture, and the dynamics of bone and wound healing. <b>Alcohol</b> Chakkalakal et al reviewed the effects of alcohol on the skeleton and fracture repair in 2005. He concluded that chronic consumption of excessive alcohol eventually results in an osteopenic skeleton. Alcoholics experience not only an increased incidence of fractures from falls, but also delays in healing compared with non-alcoholics	
<b>Carers</b>	No issues	No
<b>Human rights</b>	Will this piece of work affect anyone's human rights?	No

## Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Race	Certain ethnicities may have higher prevalence of related illness'	N/A CCG cannot influence this issue; the same criteria will apply to all patients presenting.	-	-	-
Disability	Certain ethnicities may have higher prevalence of related illness'	N/A CCG cannot influence this issue; the same criteria will apply to all patients presenting.	-	-	-
Disability	Ability to operate device in the home environment	Affected patients to be given additional support to determine whether they or their carers can operate the device in accordance with the requirements. Unsuitable patients will be offered the alternative management option involving surgery.	Acute trust clinical audit of outcomes to be presented to commissioner for all user groups.	6 monthly	CE
Sexual Orientation	LGBT people more likely to smoke	These factors are reversible and elimination improves union rates. The criteria require removal of inhibitory factors before progression to use of the device. Patients should be referred to appropriate support services ie. dietetic advice, smoking cessation services and alcohol counselling.	Acute trust clinical audit of outcomes to be presented to commissioner for all user groups.	6 monthly	CE
Age	Not appropriate for use in patients lacking skeletal maturity ie. children and adolescents	No action. These patients will be offered the alternative management option involving surgery.	N/A	-	-
Age	Age a factor in fracture repair	N/A CCG cannot influence this issue.	-	-	-
Social Deprivation	Nutrition, smoking and alcohol intake	These factors are reversible and elimination improves union rates. The criteria require removal of inhibitory factors before progression to use of the device. Patients should be referred to appropriate support services ie. dietetic advice, smoking cessation services and alcohol counselling.	Acute trust clinical audit of outcomes to be presented to commissioner for all user groups.	6 monthly	CE