

Bedfordshire and Hertfordshire Priorities Forum Guidance

Number: 54

Subject: Low Intensity Pulsed Ultrasound Therapy for Bone Healing (Exogen)

Date: November 2016

Date Review Due: November 2019

Guidance

The Exogen bone healing device is a low intensity pulsed ultrasound device which is used in an attempt to improve bone healing of fractures.

Fresh Fractures

The evidence is sufficient that Exogen could be provided **within tariff** in a fresh fracture if the clinician feels it is appropriate. No additional funding will be made available for fresh fractures.

Long Bone Non-Union

This guidance is based on recommendations in the NHS Technology Adoption Centre Publication "EXOGEN Ultrasound Bone Healing Adoption Pack". The pack follows on from NICE medical technology guidance 12 (MTG12) published in January 2013 and is focused around the recommendation that EXOGEN be utilised for patients who have suffered a long bone fracture with non-union.

EXOGEN – Money-Back Guarantee Programme

Bioventus offer a money back guarantee (applicable to the EXOGEN 4000+ model only) which, subject to terms and conditions, provides a refund of the cost of the treatment where the fracture or non-union has failed to heal after completion of the treatment. However as this offer was not included within the scope of the NICE guidance or the NICE costing template, it does not feature prominently in this pack. Adopting Trusts and patients purchasing the unit direct from the manufacturer are advised to contact Bioventus prior to the commencement of treatment to ensure that all of the stipulated conditions of the money back offer are adhered to prior to and during the treatment period.

Treatment notification and Reimbursement

Providers should apply using a localised CCG version of the form in Annex A. Providers are expected to commence treatment in agreement with the manufacturer **ONLY** if the patient meets the entry criteria. The provider is then expected to apply for reimbursement from the CCG in retrospect at the **end** of treatment when the outcomes in terms of success or failure are known, within 1 month of completion of treatment.

Entry Criteria

- The patient is over 18 years old
- The patient has a non-union fracture for > 9months and <12 months.
- The bones are well aligned and the inter-fragment gap is < 10mm.
- The patient has been screened and referred by a Consultant Radiologist/Consultant Orthopaedic Surgeon following review on at least two occasions at least 4 weeks apart to allow examination of serial x-rays.
- The patient has received a further assessment in a non-union clinic by surgeon with expertise of dealing with non-union of long bones; appropriateness of EXOGEN® has been determined through agreement of two specialist non-union Consultants

- The patient has been counselled and has the ability to comply with usage protocol and criteria in line with the EXOGEN International* Performance Program which includes a 90% minimum adherence to the treatment regimen.
- The patient is registered on the EXOGEN International* Performance Program

The CCG will only reimburse the provider if it is demonstrated within the proforma that the success criteria has been met.

Success criteria

- Radiographical Union- Defined as 3-4 cortices bridged in long bones

For treatment failures, the provider will ensure that a reimbursement is obtained in accordance with the manufacturers “money back guarantee” arrangement; the CCG will not fund these patients.

References

1. NICE Medical Technologies Guidance MTG12 “*EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing*”.
2. NHS Technology Adoption Centre Publication “EXOGEN Ultrasound Bone Healing Adoption Pack”.

Human Rights and Equalities Legislation have been considered in the formation of this guidance statement.