Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

Evidence Based Intervention

Exogen

July 2022 v1.0

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Policy.

The Exogen® ultrasound bone healing system (Smith & Nephew) delivers low intensity pulsed ultrasound waves to promote bone healing by stimulating the production of growth factors and proteins that increase the removal of old bone and the production of new bone. The procedure involves a short daily treatment using an ultrasound probe that is placed on the skin at the site of the fracture.

Recommendations -

Long Bone Non-Union

Low intensity pulsed ultrasound can be considered for treatment of long bone[1] fractures with non-union for appropriate skeletally mature patients when all of the following criteria is met:

- 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.

Long bone delayed healing

Low-intensity pulsed ultrasound for treating long bone fractures with delayed healing (no radiological evidence of healing after 3 months) is not supported by the current evidence and is considered a procedure **not normally funded**.

Fresh Fractures

The evidence for low-intensity pulsed ultrasound to promote healing of fresh fractures at low risk of non-healing does not show efficacy, therefore it is considered a procedure **not normally funded.** The evidence for low-intensity pulsed ultrasound to promote healing of fresh fractures at high risk of non-healing is very limited in quantity and quality, therefore it is considered a procedure **not normally funded.**

[1] Long-bones are defined as tibia, fibula, femur, radius, ulnar and humerus (and excludes clavicle), for the purposes of this policy, as per the evidence considered by NICE MTG12.

Rationale

This policy criteria is in alignment with the updated NICE MTG12 (2013; updated 2019), which states that 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 MTG12 also notes that the Exogen® system to treat long bone fractures with non-union is associated with an estimated cost saving of £2,407 per patient compared with current management, through avoiding surgery.

References

1. NICE IPG621 (2018): Low-intensity pulsed ultrasound to promote healing of fresh fractures at low risk of non-healing https://www.nice.org.uk/guidance/ipg621
2. NICE IPG622 (2018): Low-intensity pulsed ultrasound to promote healing of fresh fractures at high risk of non-healing https://www.nice.org.uk/guidance/ipg622
3. NICE IPG623 (July 2018): Low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures https://www.nice.org.uk/guidance/ipg623
4. NICE MTG12 (2013; updated October 2019) EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. https://www.nice.org.uk/guidance/mtg12
5. British Medical Journal (2018) Low intensity pulsed ultrasound (LIPUS) for bone healing: a clinical practice guideline https://www.bmj.com/content/356/bmj.j576

Clinical coding

This procedure (Exogen® is out of scope of the OPCS-4 classification.

ICD-10 code(s):
M84.2- Delayed union of fracture
Additional fifth character site code should be assigned if fracture site is known
Or
M84.1- Nonunion of fracture [pseudarthrosis]
Additional fifth character site code should be assigned if fracture site is known

Change History:

Version	Date	Reviewer(s)	Revision Description

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