

# Exogen<sup>®</sup> low-intensity pulsed ultrasound system for healing of non-union long bone fractures

## NHS Devon

### Commissioning policy

The use of the Exogen<sup>®</sup> low-intensity pulsed ultrasound system will be routinely commissioned in the following circumstances:

- The treatment of long bone fractures with a diagnosis of non-union, defined as failure to heal after 9 months.

### Rationale for the decision

Evidence from observational studies indicates that use of Exogen<sup>®</sup> pulsed ultrasound achieves healing in a high proportion of long bone fractures where the healing process has ceased (non-union). There is additional evidence from a randomised controlled trial demonstrating increased bone mineral density and a reduction in fracture gap area after 16 weeks treatment with Exogen<sup>®</sup>. The standard treatment for non-union fractures is currently surgery. Avoidance of the risks of surgery is desirable; the evidence base for Exogen<sup>®</sup> is considered satisfactory to support the use of this device where the specialist believes it will offer good prospects of achieving healing and thus avoiding further surgery. The use of the device is expected to incur fewer costs than surgery, particularly where the manufacturer has agreed to refund the purchase price of machines where an established non-union fracture has failed to heal after appropriate use.

It is accepted that the transition between delayed healing and non-union is difficult to define but National Institute for Health and Care Excellence (NICE) Medical Technology Guideline 12 recommends the use of Exogen<sup>®</sup> to treat long bone fractures with non-union, defined as failure to heal after 9 months.

Evidence of benefit for the use of Exogen<sup>®</sup> in other situations including delayed healing, fresh fractures or use in non- long bone fractures was considered not robust enough to support routine commissioning.

## Guidance notes on exceptionality

Where the circumstances of treatment for an individual patient do not meet the criteria described above exceptional funding can be sought. Individual cases will be reviewed by the appropriate panel of the ICB upon receipt of a completed application from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

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|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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