GMCA GREATER MANCHESTER COMBINED AUTHORITY

NHS in Greater Manchester

Greater Manchester EUR Policy Statement on:

Ultrasound and pulsed electromagnetic systems (PES) for bone healing

GM Ref: GM063

Version: 2.1 (28 January 2019)

Commissioning Statement

Ultrasound and pulsed electromagnetic systems (PES) for bone healing	
Policy Exclusions **(Alternative commissioning arrangements apply)**	Non-orthopaedic applications of pulsed electromagnetic field therapy are not covered by this policy. Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).
Policy Inclusion Criteria	Commissioned provided the device continues to be provided on a 150 day no heal (provided there is patient compliance) no fee basis for all of the following: **NOTE:** If the patient does not meet the criteria in any of the below: an individual funding request can be made if there is a good case for clinical exceptionality. Requests must be submitted with all relevant supporting evidence. **Long bone fractures with non-union (failure to heal after 9 months)** **Funding Mechanism:** Monitored approval: Referrals may be made in line with the criteria without seeking funding. **NOTE:** May be the subject of contract challenges and/or audit of cases against commissioned criteria. **Fractures of the humerus and scapula (after 4 months where there is no healing and there is significant pain at the fracture site)** **Funding Mechanism:** Individual prior approval at Clinical Triage provided the patient meets the above criteria. Requests must be submitted with all relevant supporting evidence. **Also commissioned** • All other fractures showing non-union at 9 months • Patients presenting with complex fractures (for example, an unstable or misaligned fracture or an inter-fragment gap of more than 10mm) • Cases where bones are failing to heal post surgically after the normal time period (usual 3-4 months). **NOTE:** This includes joint fusion surgery **Funding Mechanism:** Individual prior approval provided the patient meets the above criteria. Requests must be submitted with all relevant supporting evidence.
Clinical Exceptionality	Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality. Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is: • Significantly different to the general population of patients with the condition in question. ***and as a result of that difference*** • They are likely to gain significantly more benefit from the intervention than might be

	expected from the average patient with the condition.
Best Practice Guidelines	All providers are expected to follow best practice guidelines (where available) in the management of these conditions.

Contents

Policy Statement

Greater Manchester Health and Care Commissioning (GMHCC) Effective Use of Resources (EUR) Policy Team, in conjunction with the GM EUR Steering Group, have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMHCC/GM EUR Steering Group have reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

Equality & Equity Statement

GMHCC/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMHCC/CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMHCC/CCGs will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMHCC EUR Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMHCC evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Joint Commissioning Board (GMJCB) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the GM EUR Operational Policy.

Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

Rationale behind the policy statement

The range of non-union "events" where this technology can be used is expanding. In order to make the best use of the available resources to fund this type of therapy these treatments need to be targeted at those patients where there is a strong evidence base for their effectiveness.

Treatment / Procedure

Ultrasound and pulsed electromagnetic systems for bone healing are both external systems that stimulate the body's natural repair process and encourage bone growth at fracture sites. The uses for this technology are expanding so available resources to fund this type of therapy need to be targeted at those patients where there is a strong evidence base for their effectiveness. Other uses should be funded through research and development routes.

Ultrasound bone healing systems

NOTE: *EXOGEN is a brand name and is used here because it is the system that was reviewed by NICE however other versions of this type of system are available and this policy applies to them equally provided the requirements of the following paragraph are met.*

NICE in their review noted that the ultrasound signal emitted by the device (Exogen) is derived from a combination of defined electrical signal parameters and the proprietary transducer design, which generate an acoustic wave pattern specific to EXOGEN.' The clinical safety and effectiveness presented for EXOGEN should be considered only for EXOGEN and is not transferable to other LIPUS technologies. Therefore it is incumbent upon clinicians wishing to use a system other that Exogen that they first assure themselves that the evidence from the manufacturer of the clinical safety and effectiveness of the device is to the same standard as that provided in support of the Exogen system.

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. 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.

The EXOGEN system is available as two 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).

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 or their carer each day. It is intended to be used in the patient's home.

Pulsed electromagnetic field therapy

Pulsed electromagnetic field therapy is the delivery of high intensity pulsed electric field (PEF) between 2 electrodes) also called pulsed magnetic therapy, pulse magnetotherapy, or PEMF. It is a reparative technique most commonly used in the field of orthopedics for the treatment of non-union fractures, failed fusions, congenital pseudarthrosis. It does have other applications not covered by this policy.

Epidemiology and Need

In the UK there are approximately 850,000 new fractures seen each year. Rates of non-union of 5-10% of fractures have been suggested, the cost to the National Health Service of treating non-union has been reported to range between £7,000 and £79,000 per person.

A Scottish study reported that fracture non-union in the population as a whole remains low at less than 20 per 100,000 population and peaks in the fourth decade of life.[2]

NICE estimates assume that 21.4% of fractures show non-union after 9 months, around 50% of these are not suitable for EXOGEN therapy.

Adherence to NICE Guidance

This policy adheres to most of the recommendations made in NICE MTG12. However it restricts the use of this technique to the large long bones as the evidence base included in NICE MTG12 looked predominantly at fractures of these bones (Humerus, Radius, Ulna, Femur, Tibia and Fibula).

This policy also restricts the use of this technology to non-union after 9 months based on the following statement in NICE MTG12, section 6.2:

> *"For long bone fractures with **delayed healing** the Committee considered that the clinical evidence was more limited. In addition there were significant uncertainties about the rate at which healing progresses between 3 and 9 months after fracture, both with and without EXOGEN, and about whether or not surgery would be required if EXOGEN was not used. These and other considerations influenced the Committee's views about the most appropriate assumptions for cost modelling: the model considered to be most appropriate estimated that EXOGEN treatment would be more costly than current management. The Committee therefore judged that the case for adoption of EXOGEN to treat long bone fractures with delayed healing was not supported by the current evidence."*

Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

Date of Review

Five years from the date of the last review, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

Glossary

Term	Meaning
Coupling gel	A colloid in which the solid dispersephase forms a network in combination with the fluid continuous phase, resulting in a viscoussemi-rigidsol.
Electrodes	Conductors through which electricity enters or leaves an object, substance, or region.
Failed fusions	A situation in which a fracture fails to heal
Femur	The bone of the thigh articulating at the hip and the knee
Fibrous matrix	The intercellular substance of a tissue or the tissue from which a structure develops
Fibula	The outer and smaller of the two bones between the knee and the ankle
Fracture	A complete or incomplete break in a bone resulting from the application of excessive force.
Growth factors	A substance, such as a vitamin or hormone, which is required for the stimulation of growth in living cells.
Humerus	The bone of the upper arm forming joints at the shoulder and the elbow.
Mineralised bone	Deposition of calcium, hydroxylapatite salts converting osteoid to rigid bone; dependent on mineral availability (calcium, phosphate and hydrogenions), enzyme action (alkaline phosphatase), osteocyte activity (osteoblasts and osteoclasts), hormones (parathyroid hormone , thyroid calcitonin) and vitamin D.
MTG	Medical Technologies Guidance
NICE	National Institute for Health and Care Excellence
Non-union	Complete failure of a break in the bone to heal
Proteins	A class of nitrogenous organic compounds which have large molecules composed of one or more long chains of amino acids.
Pseudarthrosis	A ‘false’ joint, which can be a childhood condition (*congenital p.*) Or occur in adults when a fracture fails to unite and the bone ends are separated by fibrous tissue.
Pulsed electric field (PEF) / Pulsed electromagnetic field therapy (PEMF) / Pulsed therapy / Pulse magnetotherapy	The delivery of high intensity pulsed electric field (PEF) between 2 electrodes), is a reparative technique most commonly used in the field of orthopedics.
Radius	The thicker and shorter of the two bones in the forearm jointed at the elbow and wrist.
Tibia	The inner and typically larger of the two bones between the knee and the ankle, parallel with the fibula.
Transducer	A device that converts variations in a physical quantity, such as pressure or brightness, into an electrical signal, or vice versa.

Ulna	The thinner and longer of the two bones in the human forearm, on the side opposite to the thumb jointed at the elbow and wrist.
Ultrasound	Sound or other vibrations having an ultrasonic frequency(a frequency above the upper limit of human hearing), particularly as used in medical imaging.
Union	Joining together
Vertebrae	The small bones forming the backbone

References

1. Greater Manchester Effective Use of Resources Operational Policy
2. The relative incidence of fracture non-union in the Scottish population (5.17 million): a 5-year epidemiological study, Mills LA, Simpson AHRW, BMJ Open 2013;3:e002276. doi:10.1136/bmjopen-2012-002276

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	18/11/2015
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	12/07/2016
Greater Manchester Association Governing Group	19/07/2016
Bolton Clinical Commissioning Group	23/09/2016
Bury Clinical Commissioning Group	07/09/2016
Heywood, Middleton & Rochdale Clinical Commissioning Group	19/07/2016
Manchester Clinical Commissioning Group	Central: 01/11/2016 North: 26/08/2016 South: 01/11/2016
Oldham Clinical Commissioning Group	19/07/2016
Salford Clinical Commissioning Group	19/07/2016
Stockport Clinical Commissioning Group	19/07/2016
Tameside & Glossop Clinical Commissioning Group	03/08/2016
Trafford Clinical Commissioning Group	20/09/2016
Wigan Borough Clinical Commissioning Group	07/09/2016

Appendix 1 – Evidence Review

Ultrasound and pulsed electromagnetic systems (PES) for bone healing
GM063

Search Strategy

Searches were made using Pulsed Electromagnetic Stimulation (PEM) and then Fracture Healing & EXOGEN and then ultrasound bone healing system.

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

Database	Result
NICE	NICE MTG12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing, Published: January 2013
NHS Evidence	Ultrasound and shockwave therapy for acute fractures in adults, Griffin XL, Parsons N, Costa ML, Metcalfe D., Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD008579.
	Re-evaluation of low intensity pulsed ultrasound in treatment of tibial fractures (TRUST): randomized clinical trial, Jason W Busse, BMJ 2016;355:i5351, doi: 10.1136/bmj.i5351 (Added at review: July 2017)
Cochrane	Electromagnetic field stimulation for treating delayed union or nonunion of long bone fractures in adults, Griffin XL, Costa ML, Parsons N, Smith N., Cochrane Database of Systematic Reviews 2011, Issue 4.
	The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial, Hannemann PF, Göttgens KW, van Wely BJ, Kolkman KA, Werre AJ, Poeze M, Brink PR., J Bone Joint Surg Br. 2012 Oct;94(10):1403-8.
York	Electrical stimulation for long-bone fracture-healing: a meta-analysis of randomized controlled trials, Mollon B, da Silva V, Busse J W, Einhorn T A, Bhandari M, DOI: 10.2106/JBJS.H.00111
BMJ Clinical Evidence	Two reviews for use in ankle sprain (not cited here)
BMJ Best Practice	Items on their use in other unrelated conditions and ankle sprain (not cited here)
General Search (Google)	A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures, W. J. W. Sharrard, From the Royal Hallamshire Hospital, Sheffield, Journal of Bone and Joint surgery Vol 72B No3 May 1990
	EXOGEN Ultrasound Bone Healing System for Long Bone Fractures with Non-Union or Delayed Healing: A NICE Medical Technology Guidance, Ailish Higgins, Matthew Glover, Yaling Yang, Susan Bayliss, Catherine Meads, and Joanne Lord, Appl Health Econ Health Policy (2014) 12:477–484DOI 10.1007/s40258-014-0117-6

Medline / Open Athens	Not done for ultrasound bone healing system due to the NICE MTG being available
	Pulsed Electromagnetic Field Stimulation for Acute Tibial Shaft Fractures A Multicenter, Double-Blind, Randomized Trial, Adie S, Harris IA, Naylor JM, Rae H, Dao A, Yong S, Ying V., *J Bone Joint Surg Am*, 2011 Sep 07;93(17):1569-1576.
	Electrical Stimulation for Long-Bone Fracture-Healing: A Meta-Analysis of Randomized Controlled Trials, Mollon, Brent BHSc et al, Journal of Bone & Joint Surgery - American Volume. 90-A(11):2322-2330, November 2008

Summary of the evidence

NICE reviewed the evidence base for the use of ultrasound stimulation and found that for large long bone fractures there is evidence supportive of its use for non-union (after 9 months). They also found that the evidence of cost effectiveness for delayed union (no radiological evidence of union at 3 months) varied but that it was at worst cost neutral. This policy restricts this therapy to non-union only for the following reasons:

- NICE MTG 12 6.2 states: For long bone fractures with delayed healing the Committee considered that the clinical evidence was more limited. In addition there were significant uncertainties about the rate at which healing progresses between 3 and 9 months after fracture, both with and without EXOGEN, and about whether or not surgery would be required if EXOGEN was not used. These and other considerations influenced the Committee's views about the most appropriate assumptions for cost modelling: the model considered to be most appropriate estimated that EXOGEN treatment would be more costly than current management. The Committee therefore judged that the case for adoption of EXOGEN to treat long bone fractures with delayed healing was not supported by the current evidence.
- NICE considered the evidence base for other uses of the therapy to be limited and stated that further high quality studies were needed.
- Most of the studies and reviews found for pulsed electromagnetic stimulation (PEM) predated 2010. There was a consistent view that the evidence neither supported nor refuted the use of PEM stimulation in improving bone growth and fracture healing. All of the reviews highlighted a need for more studies to be carried out. These may not have been done as a result of the emergence of EXOGEN (a system of ultrasound stimulation of bone growth which has been shown to be effective particularly in long bone fractures – see NICE MTA12 for further info on EXOGEN).

At the time of the July 2017 review a standard rapid appraisal search was carried out looking for any evidence that postdated the first review of this policy – only one paper was found (cited below and entitled: 'Re-evaluation of low intensity pulsed ultrasound in treatment of tibial fractures (TRUST)') which did not relate to the patient groups for whom PES is currently commissioned. The study used low intensity pulsed ultrasound immediately post operatively rather than in patients who had shown previous non-union. Rates of non-union in the groups were not given. Patient compliance with treatment was moderate. NICE MTG12 had not been updated since the first review.

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies

Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

1. LEVEL 1: NICE GUIDANCE

NICE MTG12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing, Published: January 2013, www.nice.org.uk/guidance/MTG12

Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

a. 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.
b. The EXOGEN 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.
c. 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.

NB: whilst the guidance refers to long bones in general the evidence reviewed related to the larger long bones (humerus, radius, Ulna, femur, tibia and fibula) and most evidence related to the tibia and fibula.

2. LEVEL N/A: ECONOMIC APPRAISAL AND SUMMARY OF NICE MTG 12

EXOGEN Ultrasound Bone Healing System for Long Bone Fractures with Non-Union or Delayed Healing: A NICE Medical Technology Guidance, Ailish Higgins, Matthew Glover, Yaling Yang, Susan Bayliss, Catherine Meads, and Joanne Lord, Appl Health Econ Health Policy (2014) 12:477–484DOI 10.1007/s40258-014-0117-6

Abstract

The clinical evidence supports the use of EXOGEN bone healing system in non-union long bone fractures; i.e., fractures which have not healed after 9 months. The use of EXOGEN in these cases is associated with a cost saving of £1,164 per patient, due to the avoidance of surgery.

There is substantial uncertainty surrounding the use of EXOGEN bone healing system for the treatment of delayed union long bone fractures; i.e., those showing no radiological evidence of healing after3 months. The uncertainty surrounding the rate of bone healing and the necessity of surgery results in a range of potential cost consequences, some of which are cost saving and some which are not.

3. LEVEL 1: SYSTEMATIC REVIEW

Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults, Griffin XL, Costa ML, Parsons N, Smith N., *Cochrane Database of Systematic Reviews* 2011, Issue 4.

ABSTRACT

Background: Delayed union and non-union of fractures are a considerable cause of morbidity to patients. Laboratory studies have shown that electromagnetic fields can stimulate the formation of new

bone, indicating a potential role for electromagnetic stimulation in the treatment of fractures that have failed to heal.

Objectives: To assess the effects of electromagnetic stimulation for treating delayed union or non-union of long bone fractures in adults.

Search methods: We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (May 2010), the Cochrane Central Register of Controlled Trials (in *The Cochrane Library* 2010, Issue 2), MEDLINE (1966 to May 2010) and EMBASE (1980 to 2010 Week 20), trial registers and reference lists of articles.

Selection criteria: Randomised controlled trials evaluating electromagnetic field stimulation for the treatment of delayed union or non-union of long bones in adults.

Data collection and analysis: Two authors independently selected studies and performed data extraction and risk of bias assessment. Treatment effects were assessed using risk ratios and, where appropriate, data were pooled using a random-effects model.

Main results: Four studies, involving 125 participants, were included. Three studies evaluated the effects of pulsed electromagnetic fields and one study, capacitive coupled electric fields. Participants with delayed union and non-union of the long bones were included, but most data related to non-union of the tibia. Although all studies were blinded randomised placebo-controlled trials, each study had limitations. The primary measure of the clinical effectiveness of electromagnetic field stimulation was the proportion of participants whose fractures had united at a fixed time point. The overall pooled effect size was small and not statistically significant (risk ratio 1.96; 95%confidence interval 0.86 to 4.48; 4 trials). There was substantial clinical and statistical heterogeneity in this pooled analysis (I2 = 58%). A sensitivity analysis conducted to determine the effect of multiple follow-up time-points on the heterogeneity amongst the studies showed that the effect size remained non-significant at 24 weeks (risk ratio 1.61; 95% confidence interval 0.74 to 3.54; 3 trials), with similar heterogeneity (I2 = 57%). There was no reduction in pain found in two trials. No study reported functional outcome measures. One trial reported two minor complications resulting from treatment.

Authors' conclusions: Though the available evidence suggests that electromagnetic field stimulation may offer some benefit in the treatment of delayed union and non-union of long bone fractures, it is inconclusive and insufficient to inform current practice. More definitive conclusions on treatment effect await further well-conducted randomised controlled trials.

4. LEVEL 1: SYSTEMATIC REVIEW

Electrical stimulation for long-bone fracture-healing: a meta-analysis of randomized controlled trials, Mollon B, da Silva V, Busse J W, Einhorn T A, Bhandari M, DOI: 10.2106/JBJS.H.00111

CRD summary: This review concluded that no significant effect of electromagnetic stimulation on delayed unions or ununited long-bone fractures was found, but that methodological limitations and high levels of heterogeneity between studies made the impact of electromagnetic stimulation on fracture healing uncertain. This conclusion reflects the results of the review and is likely to be reliable.

Authors' objectives: To assess the effectiveness of electromagnetic stimulation on long-bone fracture healing.

Searching: MEDLINE, EMBASE, CINAHL, and all Evidence Based Medicine Reviews were searched from inception to April 2008. Search terms were reported. Seven relevant journals were also hand searched for dates ranging from 1980 to April 2008. Bibliographies of retrieved studies and other relevant publications were checked.

Study selection: Randomised controlled trials (RCTs) comparing electromagnetism of any waveform with no intervention, in patients presenting with long-bone lesions, were eligible for inclusion in the review. Eligible trials had to report the effect of the interventions on direct bone healing. Interim and subset analyses of trials published in full were excluded from the review.

Included trials assessed treatment of a range of long-bone lesions, including fracture non-unions, delayed fracture unions, tibial stress fractures, congenital pseudarthroses, fresh fractures, limb-lengthening procedures and osteotomies. Half of the included trials used electromagnetic stimulation following surgery, the other trials required full limb immobilisation. Outcomes reported related to bone union and clinical measures including pain. The majority of trials used dual external coils situated over

the bone healing site for generation of an electromagnetic field, and most also used pulsed fields with frequency ranges of 15 to 75 Hz.

Two reviewers independently selected the studies for inclusion in the review; disagreements were resolved through discussion or consultation with a third reviewer.

Assessment of study quality: The trials were independently assessed for validity by two reviewers using the following criteria: randomisation, blinding, allocation concealment, management of withdrawals and extent of follow-up. Disagreements were resolved through consensus or consultation with a third reviewer. Authors were contacted for clarification where necessary. Trials were assigned to evidence levels within the GRADE (Grading of Recommendations Assessment, Development and Evaluation) protocol.

Data extraction: Two reviewers independently extracted the data using a standardised form to permit the calculation of relative risks (RR) with 95% confidence intervals (CIs). Authors were contacted for additional clarification and data.

Methods of synthesis: The trials were combined in a meta-analysis using a DerSimonian and Laird random-effects model to calculate pooled relative risks with 95% confidence intervals. A continuity correction factor of 0.25 used for cells with zero events. Statistical heterogeneity between trials was assessed using Cochran's Q and the IP^2P statistic. Heterogeneity was explored using sensitivity analyses which excluded trials with potentially unique characteristics related to treatment methodology or duration, or to bone or bone lesion type. Where meta-analysis was not possible, a narrative synthesis was presented.

Results of the review: Eleven RCTs (n=347 patients) were included in the review. Study quality was variable. Nine RCTs blinded patients and outcome assessors and follow-up ranged from 84% to 100%, but none used an intention-to-treat analysis. Two trials reported substantial differences in participant characteristics between intervention and control groups, while three others had other methodological or reporting flaws.

Bone union (four RCTs): Meta-analysis found no statistically significant difference between the groups for bone union (RR 1.76, 95% CI: 0.8 to 3.8). There was significant statistical heterogeneity (IP^2P=60%), which was not explained by sensitivity analyses.

Clinical outcomes: No trial found any statistically significant difference between the groups for a clinical outcome, with the exception of one trial which found significant reductions in pain measures in a small subgroup of patients.

Bone densitometry: There was evidence from single trials for a positive effect of treatment on callus formation in femoral intertrochanteric osteotomies, for conservatively managed Colles fracture and for lower limb strengthening.

Authors' conclusions: The pooled analysis showed no significant effect of electromagnetic stimulation on delayed unions or ununited long-bone fractures. However, methodological limitations and high levels of heterogeneity between trials meant that the impact of electromagnetic stimulation on fracture healing was uncertain.

CRD commentary: The review question and the inclusion criteria were clear. The authors searched several relevant databases and other sources without restrictions on language. No restrictions on publication status were noted. These factors made it less likely that relevant trials were excluded or that publication or language biases were introduced. The authors reported using rigorous methodology at all stages of the review process. An appropriate validity assessment was conducted. The use of meta-analysis or narrative synthesis was guided by clinical heterogeneity, and reasonable steps were taken to assess and explore statistical heterogeneity. The authors conclusions are an accurate reflection of the results of the review and are likely to be reliable.

Implications of the review for practice and research

Practice: The authors stated that the current evidence justifies neither enthusiastic dissemination nor confident rejection of electromagnetic stimulation for bone fractures.

Research: The authors stated that appropriately sized and methodologically sound trials of electromagnetic stimulation for bone fractures were required.

5. LEVEL 2: RANDOMISED CONTROLLED TRIAL

A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures, W. J. W. Sharrard, From the Royal Hallamshire Hospital, Sheffield, Journal of Bone and Joint surgery Vol 72B No3 May 1990

A total of 45 tibial shaft fractures, all conservatively treated and with union delayed for more than 16 but less than 32 weeks were entered in a double-blind multi-centre trial. The fractures were selected for their liability to delayed union by the presence of moderate or severe displacement, angulation or comminution or a compound lesion with moderate or severe injury to skin and soft tissues. Treatment was by plaster immobilisation in all, with active electromagnetic stimulation units in 20 patients and dummy control units in 25 patients for 12 weeks. Radiographs were assessed blindly and independently by a radiologist and an orthopaedic surgeon.

Statistical analysis showed the treatment groups to be comparable except in their age distribution, but age was not found to affect the outcome and the effect of treatment was consistent for each age group. The radiologist's assessment of the active group showed radiological union in five fractures, progress to union in five but no progress to union in 10. In the control group there was union in one fracture and progress towards union in one but no progress in 23. Using Fisher's exact test, the results were very significantly in favour of the active group ($p = 0.002$).

The orthopaedic surgeon's assessment showed union in nine fractures and absence of union in 11 fractures in the active group. There was union in three fractures and absence of union in 22 fractures in the control group. These results were also significantly in favour of the active group ($p = 0.02$).

It was concluded that pulsed electromagnetic fields significantly influence healing in tibial fractures with delayed union.

6. LEVEL 3: RANDOMISED TRIAL

Pulsed Electromagnetic Field Stimulation for Acute Tibial Shaft Fractures A Multicenter, Double-Blind, Randomized Trial, Adie S, Harris IA, Naylor JM, Rae H, Dao A, Yong S, Ying V., *J Bone Joint Surg Am*, 2011 Sep 07;93(17):1569-1576.

Background: Tibial shaft fractures are sometimes complicated by delayed union and nonunion, necessitating further surgical interventions. Pulsed electromagnetic field stimulation is an effective treatment for delayed unions and nonunions, but its efficacy in preventing healing complications in patients with acute fractures is largely untested. The purpose of this pragmatic trial was to determine whether adjuvant pulsed electromagnetic field therapy for acute tibial shaft fractures reduces the rate of surgical revision because of delayed union or nonunion.

Methods: In a double-blind randomized trial involving six metropolitan trauma hospitals, 259 participants with acute tibial shaft fractures (AO/OTA type 42) were randomized by means of external allocation to externally identical active and inactive pulsed electromagnetic field devices. Participants were instructed to wear the device for ten hours daily for twelve weeks. Management was otherwise unaltered. The primary outcome was the proportion of participants requiring a secondary surgical intervention because of delayed union or nonunion within twelve months after the injury. Secondary outcomes included surgical intervention for any reason, radiographic union at six months, and the Short Form-36 Physical Component Summary and Lower Extremity Functional Scales at twelve months. Main analyses were by intention to treat.

Results:. Two hundred and eighteen participants (84%) completed the twelve-month follow-up. One hundred and six patients were allocated to the active device group, and 112 were allocated to the placebo group. Compliance was moderate, with 6.2 hours of average daily use. Overall, sixteen patients in the active group and fifteen in the inactive group experienced a primary outcome event (risk ratio, 1.02; 95% confidence interval, 0.95 to 1.14; $p = 0.72$). According to per-protocol analysis, there were six primary events (12.2%) in the active, compliant group and twenty-six primary events (15.1%) in the combined placebo and active, noncompliant group (risk ratio, 0.97; 95% confidence interval, 0.86 to 1.10; $p = 0.61$). No between-group differences were found with regard to surgical intervention for any reason, radiographic union, or functional measures.

Conclusions:. Adjuvant pulsed electromagnetic field stimulation does not prevent secondary surgical interventions for delayed union or nonunion and does not improve radiographic union or patient-reported functional outcomes in patients with acute tibial shaft fractures.

7. LEVEL 1: META-ANALYSES

Electrical Stimulation for Long-Bone Fracture-Healing: A Meta-Analysis of Randomized Controlled Trials, Mollon, Brent BHSc et al, Journal of Bone & Joint Surgery - American Volume. 90-A(11):2322-2330, November 2008

Background: Bone stimulation represents a $500 million market in the United States. The use of electromagnetic stimulation in the treatment of fractures is common; however, the efficacy of this modality remains uncertain. We conducted a systematic review and meta-analysis of randomized controlled trials to evaluate the effect of electromagnetic stimulation on long-bone fracture-healing.

Methods: We searched four electronic databases (MEDLINE, EMBASE, CINAHL, and all Evidence-Based Medicine Reviews) for trials of electromagnetic stimulation and bone repair, in any language, published from the inception of the database to April 2008. In addition, we searched by hand seven relevant journals published between 1980 and April 2008 and the bibliographies of eligible trials. Eligible trials enrolled patients with long-bone lesions, randomly assigned them to electromagnetic stimulation or a control group, and reported on bone-healing. Information on the methodological quality, stimulation device, duration of treatment, patient demographics, and all clinical outcomes were independently extracted by two reviewers.

Results: Of 2546 citations obtained in the literature search, eleven articles met the inclusion criteria. Evidence from four trials reporting on 106 delayed or ununited fractures demonstrated an overall non significant pooled relative risk of 1.76 (95% confidence interval, 0.8 to 3.8; p = 0.15; I2 = 60.4%) in favor of electromagnetic stimulation. Single studies found a positive benefit of electromagnetic stimulation on callus formation in femoral intertrochanteric osteotomies, a limited benefit for conservatively managed Colles fracture or for lower limb-lengthening, and no benefit on limb-length imbalance and need for reoperation in surgically managed pseudarthroses or on time to clinical healing in tibial stress fractures. Pain was reduced in one of the four trials assessing this outcome

Conclusions: While our pooled analysis does not show a significant impact of electromagnetic stimulation on delayed unions or ununited long-bone fractures, methodological limitations and high between-study heterogeneity leave the impact of electromagnetic stimulation on fracture-healing uncertain.

8. LEVEL 2: RANDOMISED CONTROLLED TRIAL

The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial, Hannemann PF, Göttgens KW, van Wely BJ, Kolkman KA, Werre AJ, Poeze M, Brink PR., J Bone Joint Surg Br. 2012 Oct;94(10):1403-8.

Description: The use of pulsed electromagnetic fields (PEMF) to stimulate bone growth has been recommended as an alternative to the surgical treatment of ununited scaphoid fractures, but has never been examined in acute fractures. We hypothesised that the use of PEMF in acute scaphoid fractures would accelerate the time to union by 30% in a randomised, double-blind, placebo-controlled, multicentre trial. A total of 53 patients in three different medical centres with a unilateral undisplaced acute scaphoid fracture were randomly assigned to receive either treatment with PEMF (n = 24) or a placebo (n = 29). The clinical and radiological outcomes were assessed at four, six, nine, 12, 24 and 52 weeks. A log-rank analysis showed that neither time to clinical and radiological union nor the functional outcome differed significantly between the groups. The clinical assessment of union indicated that at six weeks tenderness in the anatomic snuffbox (p = 0.03) as well as tenderness on longitudinal compression of the scaphoid (p = 0.008) differed significantly in favour of the placebo group. **We conclude that stimulation of bone growth by PEMF has no additional value in the conservative treatment of acute scaphoid fractures.**

9. LEVEL 1: SYSTEMATIC REVIEW

Ultrasound and shockwave therapy for acute fractures in adults, Griffin XL, Parsons N, Costa ML, Metcalfe D., *Cochrane Database of Systematic Reviews* 2014, Issue 6. Art. No.: CD008579.

Background: The morbidity and socioeconomic costs of fractures are considerable. The length of time to healing is an important factor in determining a person's recovery after a fracture. Ultrasound may have a therapeutic role in reducing the time to union after fracture. This is an update of a review previously published in February 2012.

Objectives: To assess the effects of low-intensity ultrasound (LIPUS), high-intensity focused ultrasound (HIFUS) and extracorporeal shockwave therapies (ECSW) as part of the treatment of acute fractures in adults.

Search methods: We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (2 June 2014), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2014, Issue 5), MEDLINE (1946 to May Week 3 2014), EMBASE (1980 to 2014 Week22), trial registers and reference lists of articles.

Selection criteria: Randomised and quasi-randomised controlled trials evaluating ultrasound treatment in the management of acute fractures in adults. Studies had to include participants over 18 years of age with acute fractures, reporting outcomes such as function; time to union; nonunion; secondary procedures such as for fixation or delayed union or non-union; adverse effects; pain; costs; and patient adherence.

Data collection and analysis: Two authors independently extracted data from the included studies. Treatment effects were assessed using mean differences, standardised mean differences or risk ratios using a fixed-effect model, except where there was substantial heterogeneity, when data were pooled using a random-effects model. Results from 'worst case' analyses, which gave more conservative estimates of treatment effects for time to fracture union, are reported in preference to those from 'as reported' analyses.

Main results: We included 12 studies, involving 622 participants with 648 fractures. Eight studies were randomised placebo-controlled trials, two were randomised controlled trials without placebo controls, one was a quasi-randomised placebo-controlled trial and one was a quasi randomised controlled trial without placebo control. Eleven trials tested LIPUS and one trial tested ECSW. Four trials included participants with conservatively treated upper limb complete fractures and six trials included participants with lower limb complete fractures; these were surgically fixed in four trials. The remaining two trials reported results for conservatively treated tibial stress fractures. 'Risk of bias' assessment of the included studies was hampered by the poor reporting of methods, frequently resulting in the risk of bias of individual domains being judged as 'unclear'. Both quasi-randomised studies were at high risk of bias, including selection and attrition bias. Three studies were at low risk of selection bias relating to allocation concealment the majority of studies were at low risk of performance bias as they employed a form of intervention blinding. Only limited data were available from three of only four studies reporting on functional outcome. One study of complete fractures found little evidence of a difference between the two groups in the time to return to work (mean difference (MD) 1.95 days favouring control, 95%confidence interval (CI) -2.18 to 6.08; 101 participants). Pooled data from two studies found LIPUS did not significantly affect the time to return to training or duty in soldiers or midshipmen with stress fractures (MD -8.55 days, 95% CI -22.71 to 5.61;93 participants).We adopted a conservative strategy for data analysis that was more likely to underestimate than to overestimate a benefit of the intervention. After pooling results from eight studies (446 fractures), the data showed no statistically significant reduction in time to union of complete fractures treated with LIPUS (standardised mean difference (SMD) -0.47, 95% CI -1.14 to 0.20). This result could include a clinically important benefit or harm, and should be seen in the context of the highly significant statistical heterogeneity (I^2 =90%). This heterogeneity was not explained by the a priori subgroup analyses (upper limb versus lower limb fracture, smoking status).An additional subgroup analysis comparing conservatively and operatively treated fractures raised the possibility that LIPUS may be effective in reducing healing time in conservatively managed fractures, but the test for subgroup differences did not confirm a significant difference between the subgroups. Pooled results from five of the eight trials (333 fractures) reporting proportion of delayed union or non-union showed no significant difference between LIPUS and control (10/168 versus 13/165; RR 0.75; 95% CI 0.24 to 2.28). Adverse effects directly associated with LIPUS

and associated devices were found to be few and minor, and compliance with treatment was generally good. One study reporting on pain scores found no difference between groups at eight weeks (101 participants).One quasi-randomised study found no significant difference in non-union at 12 months between internal fixation supplemented with ECSW and internal fixation alone (3/27 versus 6/30; RR 0.56, 95% CI 0.15 to 2.01). There was a clinically small but statistically significant difference in the visual analogue scores for pain in favour of ECSW at three month follow-up (MD -0.80, 95% CI -1.23 to-0.37). The only reported complication was infection, with no significant difference between the two groups.

Authors' conclusions: While a potential benefit of ultrasound for the treatment of acute fractures in adults cannot be ruled out, the currently available evidence from a set of clinically heterogeneous trials is insufficient to support the routine use of this intervention in clinical practice. Future trials should record functional outcomes and follow-up all trial participants.

10. LEVEL 2: RANDOMISED CONTROLLED TRIAL

Re-evaluation of low intensity pulsed ultrasound in treatment of tibial fractures (TRUST): randomized clinical trial, Jason W Busse, BMJ 2016;355:i5351, doi: 10.1136/bmj.i5351

ABSTRACT

Objective: To determine whether low intensity pulsed ultrasound (LIPUS), compared with sham treatment, accelerates functional recovery and radiographic healing in patients with operatively managed tibial fractures.

Design: A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 501 patients, enrolled between October 2008 and September 2012, and followed for one year.

Setting: 43 North American academic trauma centers.

Participants: Skeletally mature men or women with an open or closed tibial fracture amenable to intramedullary nail fixation. Exclusions comprised pilon fractures, tibial shaft fractures that extended into the joint and required reduction, pathological fractures, bilateral tibial fractures, segmental fractures, spiral fractures >7.5 cm in length, concomitant injuries that were likely to impair function for at least as long as the patient's tibial fracture, and tibial fractures that showed <25% cortical contact and >1 cm gap after surgical fixation. 3105 consecutive patients who underwent intramedullary nailing for tibial fracture were assessed, 599 were eligible and 501 provided informed consent and were enrolled.

Interventions: Patients were allocated centrally to self administer daily LIPUS (n=250) or use a sham device (n=251) until their tibial fracture showed radiographic healing or until one year after intramedullary fixation.

Main outcome measures: Primary registry specified outcome was time to radiographic healing within one year of fixation; secondary outcome was rate of non-union. Additional protocol specified outcomes included short form-36 (SF-36) physical component summary (PCS) scores, return to work, return to household activities, return to ≥80% of function before injury, return to leisure activities, time to full weight bearing, scores on the health utilities index (mark 3), and adverse events related to the device.

Results: SF-36 PCS data were acquired from 481/501 (96%) patients, for whom we had 2303/2886 (80%) observations, and radiographic healing data were acquired from 482/501 (96%) patients, of whom 82 were censored. Results showed no impact on SF-36 PCS scores between LIPUS and control groups (mean difference 0.55, 95% confidence interval −0.75 to 1.84; P=0.41) or for the interaction between time and treatment (P=0.30); minimal important difference is 3-5 points) or in other functional measures. There was also no difference in time to radiographic healing (hazard ratio 1.07, 95% confidence interval 0.86 to 1.34; P=0.55). There were no differences in safety outcomes between treatment groups. Patient compliance was moderate; 73% of patients administered ≥50% of all recommended treatments.

Conclusions: Postoperative use of LIPUS after tibial fracture fixation does not accelerate radiographic healing and fails toimprove functional recovery.

Appendix 2 – Diagnostic and Procedure Codes

Ultrasound and pulsed electromagnetic systems (PES) for bone healing
GM063

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

GM063 - Ultrasound and pulsed electromagnetic systems (PES) for bone healing	
There are no appropriate OPCS-4 codes to reflect ultrasound and pulsed electromagnetic systems.	
The ICD-10 code for non-union fracture is:	
Nonunion of fracture [pseudarthrosis]	M84.1

Appendix 3 – Version History

Ultrasound and pulsed electromagnetic systems (PES) for bone healing
GM063

The latest version of this policy can be found here: GM Ultrasound and Pulsed Electromagnetic Systems (PES) for bone healing policy

Version	Date	Summary of Changes
0.1	03/01/2015	Initial draft
0.2	26/01/2015	Amendments made after GM EUR Steering Group on 21/01/2015: • Section 4 – Criteria for Commissioning: Line under mandatory criteria removed *'large long bone fractures with delayed healing (no radiological evidence of healing after approximately 3 months)'* • Section 6 – Evidence Summary: Section added re. NICE MTG 12 and why this policy restricts to non-union only. • Section 8 – Adherence to NICE Guidance: Section expanded as to how policy mostly adheres to NICE MTG 12.
0.3	09/03/2015	The following safety amendment paragraph added in Section 2 under Ultrasound Bone Healing Systems following receipt of email from Bioventus Global: *'NICE In their review noted that the ultrasound signal emitted by the device (Exogen) is derived from a combination of defined electrical signal parameters and the proprietary transducer design, which generate an acoustic wave pattern specific to EXOGEN.' The clinical safety and effectiveness presented for EXOGEN should be considered only for EXOGEN and is not transferable to other LIPUS technologies. Therefore it is incumbent upon clinicians wishing to use a system other that Exogen that they first assure themselves that the evidence from the manufacturer of the clinical safety and effectiveness of the device is to the same standard as that provided in support of the Exogen system.'*
1.0	18/11/2015	On the 18th November 2015 following review of the feedback from the period of clinical engagement the GM EUR Steering made the following changes to the policy:- • The Mandatory Criteria was updated to read as follows:- *'Ultrasound bone healing systems are commissioned for patients who meet the following criteria:* • *large long bone fractures with non-union (failure to heal after 9 months)* *Provided the device continues to be provided on a 150 day no heal (provided there is patient compliance) no fee basis then the following will also be commissioned.* *Individual Prior Approval should be sought prior to treatment from the North West Commissioning Support Unit IFR Team for:-* • *All other fractures showing non-union at 9 months* • *Patients presenting with complex (for example, an unstable or misaligned fracture or an inter-fragment gap of more than 10 mm) fractures.* • *Treatment for fractures of the Humerus and Scapula after 4 months where there is no healing and there is significant pain at the fracture site via prior approval (at the triage stage of the IFR process).* • *Cases where bones are failing to heal post surgically after the normal time period (usual 3-4 months). NOTE this includes joint fusion surgery'* • The Funding Mechanism section updated to read as follows:- *'Via Monitored Approval for patients with large long bone fractures with non-*

		union (failure to heal after 9 months) provided the device continues to be provided on a 150 day no heal (provided there is patient compliance) no fee basis then the following will also be commissioned. *Individual Prior Approval should be sought prior to treatment from the North West Commissioning Support Unit IFR Team for:-* • *All other fractures showing non-union at 9 months* • *Patients presenting with complex (for example, an unstable or misaligned fracture or an inter-fragment gap of more than 10 mm) fractures.* • *Treatment for fractures of the Humerus and Scapula after 4 months where there is no healing and there is significant pain at the fracture site via prior approval (at the triage stage of the IFR process).* • *Cases where bones are failing to heal post surgically after the normal time period (usual 3-4 months).NOTE this includes joint fusion surgery* *Clinicians can submit an Individual Funding Request (IFR) if they feel there is a good case for exceptionality.'* Subject to the above changes had been made the GM EUR Steering Group approved the policy to go through the governance process.
1.1	20/01/2016 15/03/2016	Following GM EUR Steering Group on 20/01/2016 the wording for date of review changed to read as follows: *'One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group. (Unless stated this will be every 2 years).'* Policy updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.
1.2	19/07/2016	Diagnostic and Procedure Codes added as Appendix 2
2.0	19/07/2017	Following scheduled review at GM EUR Steering Group on 19 July 2017 the following amendments were agreed: • Policy updated to new format. • <u>Policy Inclusion Criteria:</u> Wording and funding mechanisms amended for clarity. • <u>Treatment/Procedure:</u> Under the heading 'Ultrasound bone healing systems', the words *'or their carer'* added after *'patient' near the end of the last paragaraph*. • <u>Date of Review:</u> Section amended to include standard wording and that next review will be in five years. • <u>Appendix 1 - Evidence Review:</u> o One citation added to 'Search Strategy' table and a summary added to 'The Evidence'. o Paragraph added to end of 'Summary of the evidence' summarising what was found in July 2017 review search.
2.1	28/01/2019	• Branding changed to reflect change of service from Greater Manchester Shared Services to Greater Manchester Health and Care Commissioning. • Links updated as documents have all moved to a new EUR web address. • <u>Commissioning Statement:</u> o *'(Alternative commissioning arrangements apply)'* added after Policy Exclusions o *'Best Practice Guideline'* section added