NHS BOLTON CLINICAL COMMISSIONING GROUP  
Public Board Meeting

AGENDA ITEM NO: ..........9(a).................

Date of Meeting: ..........23rd September 2016..........

<table>
<thead>
<tr>
<th>TITLE OF REPORT:</th>
<th>Update on Pain Management Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTHOR:</td>
<td>Jennifer Riley, Senior Commissioning Manager</td>
</tr>
<tr>
<td>PRESENTED BY:</td>
<td>Barry Silvert, Clinical Director for Commissioning</td>
</tr>
<tr>
<td>PURPOSE OF PAPER:</td>
<td>Following the development of a new, evidence-based service specification for Pain Management services, both BMI Beaumont and Bolton NHS Foundation Trust were required to provide their responses to this specification, with information on how their service complied with this. The Board approved in June 2016 the assurance process to ensure that both providers are able to meet the specification. Following this, both providers were formally written to, detailing what was required for the Board to be assured of their service provision. This paper provides an update on provider responses and progress to date.</td>
</tr>
<tr>
<td>RECOMMENDATION TO THE BOARD:</td>
<td>The Board is asked to note the action plans received and progress to date</td>
</tr>
<tr>
<td>COMMITTEES/GROUPS PREVIOUSLY CONSULTED:</td>
<td>CCG Executive CCG Board</td>
</tr>
<tr>
<td>REVIEW OF CONFLICTS OF INTEREST:</td>
<td>No CCG conflicts identified in commissioning process</td>
</tr>
<tr>
<td>OUTCOME OF EQUALITY IMPACT ASSESSMENT (EIA) AND ANY ASSOCIATED RISKS:</td>
<td>EIA completed.</td>
</tr>
</tbody>
</table>
Update on Pain Management services

Background
NHS Bolton CCG currently commissions Pain Management services from two providers, Bolton NHS Foundation Trust and BMI Beaumont Hospital, with patients requiring tertiary level input being referred to Salford Royal NHS Foundation Trust. There has not historically been a Pain Management service specification in place, and it has been difficult for commissioners to monitor the quality and outcomes of the services. As such, a Pain Management service specification was developed in Summer 2015, with the main aims of:

- Providing a biopsychosocial approach to Pain Management, supported by a comprehensive MDT, as outlined in national guidance and best practice
- Ensuring compliance with EUR policies
- Monitoring compliance with GIMMG formulary

Update
BMI Beaumont and Bolton NHS FT were asked to respond to the service specification as to how they could meet this. Responses were reviewed by the Board, and assurance was provided that both providers could work towards this. However, some specific development areas were identified for each provider. As such, both providers were formally written to in July 2016, outlining the areas for further development and requesting action plans in response.

Both providers have responded accordingly with their action plans, which can be found in Appendices 1 and 2. BMI Beaumont have advised that their full service will be up and running from the beginning of October 2016, due to the need to ensure that the full MDT structure is in place. The Commissioning and Quality teams have reviewed this timescale in conjunction with the action plan submitted, and have agreed to this approach.

The BFT action plan does require some further joint work with the Commissioning team, and as such, a joint meeting has been set up for 19th September to further clarify outcome measures and the cost benefit analysis for Pain Management Programmes.

There have been some issues in KPI reporting from the end of August for both providers, due to some of the systems and pathways required to be in place. These will be submitted from the end of September 2016.
## Progress against milestones

<table>
<thead>
<tr>
<th>Action</th>
<th>Timescale</th>
<th>Update</th>
<th>Lead</th>
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</thead>
<tbody>
<tr>
<td>Commissioning team to meet with BMI Beaumont to discuss action plan and timescales</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; July 2016</td>
<td>Complete (completed remotely)</td>
<td>CCG</td>
</tr>
<tr>
<td>Confirmation of outcome measures against which service will be monitored</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; July 2016</td>
<td>Complete</td>
<td>CCG</td>
</tr>
<tr>
<td>CCG and Provider BI and Contracting teams to confirm KPI reporting formats</td>
<td>18&lt;sup&gt;th&lt;/sup&gt; July 2016</td>
<td>Complete</td>
<td>CCG / BMI</td>
</tr>
<tr>
<td><strong>Formal action plan including timescales for recruitment, implementation of new pathway, and development of audit programme, to be submitted to the CCG</strong></td>
<td>18&lt;sup&gt;th&lt;/sup&gt; July 2016</td>
<td>Complete</td>
<td>BMI</td>
</tr>
<tr>
<td><strong>Formal action plan including timescales for review of N:FU ratios; PMP cost benefit analysis; and staffing review to be submitted to the CCG</strong></td>
<td>18&lt;sup&gt;th&lt;/sup&gt; July 2016</td>
<td>Complete</td>
<td>BFT</td>
</tr>
<tr>
<td>Contractual monitoring and escalation process to be confirmed</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; August 2016</td>
<td>Complete</td>
<td>CCG</td>
</tr>
<tr>
<td><strong>Evidence of MDT structure, including named Clinical Psychologist, to be in place</strong></td>
<td>29&lt;sup&gt;th&lt;/sup&gt; August 2016</td>
<td>Complete</td>
<td>BMI</td>
</tr>
<tr>
<td>Submission of first KPI reports</td>
<td>29th August 2016*</td>
<td>30&lt;sup&gt;th&lt;/sup&gt; September 2016</td>
<td>BMI / BFT</td>
</tr>
</tbody>
</table>
**NHS BOLTON CLINICAL COMMISSIONING GROUP**

**Public Board Meeting**

**AGENDA ITEM:  ....9(b).........**

Date of Meeting: .....23rd September 2016.....

<table>
<thead>
<tr>
<th>TITLE OF REPORT:</th>
<th>Mental Health - Out of Area Treatment (OAT) placements Report</th>
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<tbody>
<tr>
<td>AUTHOR:</td>
<td>Rachael Sutton, Senior Commissioning Manager – Mental Health</td>
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<tr>
<td></td>
<td>Melissa Laskey, Associate Director of Commissioning</td>
</tr>
<tr>
<td>PRESENTED BY:</td>
<td>Barry Silvert, Clinical Director of Commissioning</td>
</tr>
<tr>
<td>PURPOSE OF PAPER: (Linking to Strategic Objectives)</td>
<td>This paper provides an update to CCG Board on the mental health Out of Area Placements and plans for the development of a local service for appropriate patients</td>
</tr>
<tr>
<td>LINKS TO CORPORATE OBJECTIVES (tick relevant boxes):</td>
<td>Delivery of Year 1 Locality Plan.</td>
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<td></td>
<td>Joint collaborative working with Bolton FT and the Council.</td>
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<td>Supporting people in their home and community. √</td>
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<td>Shared health care records across Bolton.</td>
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<td>Regulatory Requirement</td>
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<td>Standing Item</td>
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<tr>
<td>RECOMMENDATION TO THE BOARD: (Please be clear if decision required, or for noting)</td>
<td>For approval to progress the development of a Business Case which, if supported, would support a GMW/Alternative Futures locked rehab pilot in Bolton</td>
</tr>
<tr>
<td>COMMITTEES/GROUPS PREVIOUSLY CONSULTED:</td>
<td>CCG Executive</td>
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<tr>
<td></td>
<td>GMW Executive</td>
</tr>
<tr>
<td>REVIEW OF CONFLICTS OF INTEREST:</td>
<td>None noted at present</td>
</tr>
<tr>
<td>VIEW OF THE PATIENTS, CARERS OR THE PUBLIC, AND THE EXTENT OF THEIR INVOLVEMENT:</td>
<td>Whilst patients, carers and the wider public have not been consulted specifically about localising pathways if agreed by Board engagement with relevant service user and carer groups will be undertaken. Informal engagement with current service users (in out of area facilities) has highlighted that all would support a locally provided service</td>
</tr>
<tr>
<td>OUTCOME OF EQUALITY IMPACT ASSESSMENT (EIA) AND ANY ASSOCIATED RISKS:</td>
<td>To be undertaken following wider consultation.</td>
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Mental Health Out of Area Placements

1. Purpose of Paper

1.1 This paper provides an update to CCG Board on the position with Mental Health patients requiring specialist care who are currently placed in Out of Area facilities due to the lack of clinically appropriate facilities within Bolton.

1.2 The CCG Board is asked to review the paper and specifically endorse the proposal to develop a Business Case which, if supported, would see the collaboration of Greater Manchester West (GMW) NHS Foundation Trust and Alternative Futures (as the two current providers of inpatient specialist mental health provision on Bolton) on delivery of a new 12-14 bed “locked” rehabilitation unit in Bolton to accommodate patients who are otherwise placed out of area.

1.3 The primary reason for this proposal is to deliver the specialist care needed as close to people’s home as possible. Some current placements are as far away as Durham, which means people are cut off from friends and family. Generally patients have expressed a strong desire to be in a location in Bolton and the evidence based shows a strong correlation between people being in placements closer to home and their outcomes, particularly in how quickly they can move into open rehabilitation units and back home.

2. Background Information

2.1 Overview of Mental Health commissioned services

The current mental health landscape in Bolton is made up of a variety of provision to address all age emotional wellbeing and mental health issues, ranging from acute in-patient and open rehab beds, specialist out-patient clinics (including adult ADHD, Eating Disorders and CAMHS), and a number of independent and voluntary sector providers offering primary and secondary mental health input through groups, talking therapies, day centre provision and crisis support. Services are commissioned by Bolton CCG, Bolton Council (Commissioning and Public Health), NHS England and national charitable organisations.

This paper centres around adult mental health in-patient services (commissioned by the CCG) with a specific focus on the over performance of Out of Area Treatment (OATs) placements which is the second tier of service provision as set out in Diagram 1 below.

Diagram 1: Mental Health provision based on need
3. **Current Position**

3.1 **Action to Date**

There are currently 57 individuals who are in Out of Area specialist facilities.

An in depth review of the process for assessing and securing placements has been undertaken, which has resulted in the following positive actions being completed:

- Assessment of all patients has been undertaken which has resulted in the funding panel in agreeing appropriate placements based on patient mix, speciality and physical environment of the unit and experience of staff.
- A robust process has been put in place to ensure multi-disciplinary assessment of individual needs with appropriate care placements being commissioned and each patient being allocated a Care Co-ordinator.
- This MDT needs assessment forms the basis of the placement request and 3 independent assessments are required. Funding decisions are subsequently based on proximity to home, best value, best outcomes and where possible (given the client group are largely detained under the Mental Health Act with specialised needs) patient and carer’s views.
- The CCG now has a designated mental health contracts manager, BI officer, finance officer and Senior Commissioning Manager who all have specific responsibility for mental health. Monthly meetings are held between all these professionals to share information.
- The contracts department are in the process of ensuring all OATs providers have a standard NHS contract in place to ensure monitoring, data flows and activity information in addition to the relevant contract levers can be used in the event of quality or performance issues. As a wider team we are working towards outcome based contracts directly linked to payments.
- Quarterly contract monitoring meetings are now in place with monthly liaison meetings in the interim period to consider any activity of note, changes of need and delays in the discharge process.

3.2 **Issues requiring Resolution**

Despite the above actions, OATs numbers continue to increase due to more complex presentations attributed to drug and alcohol use, PTSD, psycho-active substances (legal highs), increased awareness of mental health, and in the older population an increase in dementia prevalence rates due to the population living longer. Chart 1 below provides an overview of patient numbers year on year with an estimated direction of travel in the current climate.

*Chart 1: number of OOA placements year on year*
Whilst the majority of OATS placements are within the North West, there are smaller number of patients placed at a significant distance from home, friends and family, and care coordinators. The furthest being Durham and West Bromwich, the reasons primarily around a lack of highly specialised units in the North West. Diagram 2 below shows the location map of placements in relation to Bolton and Greater Manchester region.

Diagram 2: Current OATs placements

4. Proposed Actions

The following actions are required to support the reduction in the number of mental health OATs, repatriate patients (where safe and appropriate), and provide high quality, cost effective local services for local people in line with the locality plan. This would provide the opportunity to also look to address the specific issue with the provision of female locked rehab services.

4.1 OATs locked rehab pilot

As highlighted earlier in this report, there are 57 service users current placed out of area with a range of needs that are either fully or partly health funded. The main OAT group at present is women, particularly those with complex needs.

Recent assessment information available indicates a possible 19 female patients currently placed out of area that may be suitable for a local locked rehab services.

Therefore the CCG is currently working with GMW on a proposal to pilot a new 12 -14 bed unit within Bolton to enable repatriation of Bolton residents and enable them to be closer to home. Hawthorn House, a vacant building owned by GMW on the RBH site has been identified as a potential local option for the proposed unit. This is being taken to GMW Board for approval in principle (an estimated £1.7 – 1.9m refurbishment programme).
A business case is in development to demonstrate the cost effectiveness of a new care model provided in Bolton by GMW and Alternative Futures. The current average cost of an OATs placement is £127k per annum, and the indicative estimated cost for equivalent care £120k through the proposed pilot (this is subject to a fully worked up costed model).

The benefits of this pilot are:

- Patients being close to family and friends and their support networks at a time they need them the most
- Patients will be able to be “stepped down” into the most appropriate, least restrictive setting far more quickly and in a streamlined way if GMW and Alternative Futures (current providers of the 12 bed open rehab mental health facility at Oak Lodge, Little Lever) work together on an enhanced service delivery model
- Better use of the Bolton £ - with a reduction in out of area placement costs by providing better value placements within Bolton area and stepping patients down more quickly
- Improved local mental health pathway with improved links to care coordinators as GMW will manage the entire pathway from community through to acute and specialist care
- Assurance that all placements are person-centred and of high quality
- Local PLACE based services with strengthened capacity to meet complex needs – in line with the Greater Manchester strategy
- Building identified in close proximity to the acute wards
- Reduce number of OATs in the longer term through improved local investment in mental health service and in line with parity of esteem agenda

Some potential risks have been identified (such as the cost of refurbishing the unit). The Business Case will ensure that all identified risks can be mitigated as far as possible.

5. Recommendation

5.1 The CCG Board is asked to review the paper and specifically endorse the proposal to develop a Business Case which, if supported, would see the collaboration of Greater Manchester West (GMW) NHS Foundation Trust and Alternative Futures on delivery of a new 12-14 bed “locked” rehabilitation unit in Bolton to accommodate patients who are otherwise placed out of area.

Rachael Sutton
Senior Commissioning Manager for Mental Health

Melissa Laskey
Associate Director of Commissioning

10th September 2016
NHS BOLTON CLINICAL COMMISSIONING GROUP
Public Board Meeting

AGENDA ITEM NO: ........9 (c) to (d)..................

Date of Meeting: ......23rd September 2016........................

<table>
<thead>
<tr>
<th>TITLE OF REPORT:</th>
<th>Commissioning Decisions:</th>
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<tr>
<td></td>
<td>• Ultrasound and pulsed electromagnetic systems (PES).</td>
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<tr>
<td></td>
<td>• Facet Joint Injections for Back and Neck Pain/Radiofrequency Denervation for Back and Neck Pain.</td>
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<table>
<thead>
<tr>
<th>AUTHOR:</th>
<th>Michael Robinson, Associate Director Integrated Governance &amp; Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRESENTED BY:</td>
<td>Colin Mercer, Clinical Director, Clinical Governance &amp; Safety</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PURPOSE OF PAPER: (Linking to Strategic Objectives)</th>
<th>To update the Board on the policies that have been through the agreed GM EUR Governance arrangements and were approved by the AGG in April 2016:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Ultrasound and pulsed electromagnetic systems (PES) for bone healing – currently no policy in Bolton and this policy will be subject to prior approval. Although the new policy will lead to an estimated increased procedural cost of £66, the health economy saving i.e. reduced theatre time, bed days and complications is significantly greater.</td>
</tr>
<tr>
<td></td>
<td>• Facet Joint Injections for Back and Neck Pain/ Radiofrequency Denervation for Back and Neck Pain – currently no policies in Bolton and these policies will be subject to prior approval against mandatory criteria. This will lead to an estimated saving within Bolton of £36K.</td>
</tr>
</tbody>
</table>

The policies approved by the AGG are still required to be ratified by CCG governing bodies as the AGG isn’t a statutory organisation and therefore can’t decide policy. It is assumed that because the policy has already been through a rigorous governance process, ratification at governing bodies will be straightforward. Once approved by the Board, these policies will be published on the CCG website.
| **RECOMMENDATION TO THE BOARD:**  
(Please be clear if decision required, or for noting) | The Board is asked to ratify the approval of the attached commissioning policies. |
|--------------------------------------------------------|---------------------------------------------------------------------------------|
| **COMMITTEES/GROUPS PREVIOUSLY CONSULTED:**            | GM Association of CCGs.  
CCG Executive. |
| **REVIEW OF CONFLICTS OF INTEREST:**                  | Conflicts of interest are reviewed as part of the consultation process. |
| **VIEW OF THE PATIENTS, CARERS OR THE PUBLIC, AND THE EXTENT OF THEIR INVOLVEMENT:** | Patient views are not specifically sought as part of this report. |
| **OUTCOME OF EQUALITY IMPACT ASSESSMENT (EIA) AND ANY ASSOCIATED RISKS:** | EIA and an assessment is not considered necessary for the report. |
Title/Topic: Ultrasound and pulsed electromagnetic systems (PES) for bone healing
Reference: GM063
Date: November 2015
### Version Control

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<tr>
<td>0.1</td>
<td>03/01/2015</td>
<td>Initial draft</td>
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</table>
| 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. | 8           |
|         | 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. | 7           |
| 1.0     | 10/12/2015 | 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:  
- 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 Humorous 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 | 9           |
- 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 Humorous 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.

<table>
<thead>
<tr>
<th>1.1</th>
<th>20/01/2016</th>
<th>Following GM EUR Steering Group on 20/01/2016 the wording for date of review changed to read as follows:</th>
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<tbody>
<tr>
<td></td>
<td>15/03/2016</td>
<td>Policy updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.</td>
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</table>
# POLICY STATEMENT

**Title/Topic:** Ultrasound and pulsed electromagnetic systems for bone healing

**Issue Date:** Insert Month and Year approved by AGG

## Commissioning Recommendation:
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 Greater Manchester Shared Services (GMSS) 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 Humorous 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.

See Section 4: Criteria for Commissioning

## Date of Review:
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).

## Prepared By:
Greater Manchester Shared Services Effective Use of Resources Policy Team
<table>
<thead>
<tr>
<th>Approved By</th>
<th>Date Approved</th>
<th>Funding Mechanism</th>
</tr>
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</table>
| Greater Manchester Effective Use of Resources Steering Group | 18/11/2015    | GM EUR Steering Group recommended funding mechanism: 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 Humorous 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. |
<p>| Greater Manchester Chief Finance Officers/Greater Manchester Heads of Commissioning | N/A           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Greater Manchester Association Governing Group        | N/A           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Bury Clinical Commissioning Group                     |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Bolton Clinical Commissioning Group                   |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Heywood, Middleton &amp; Rochdale Clinical Commissioning Group |             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Central Manchester Clinical Commissioning Group       |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| North Manchester Clinical Commissioning Group         |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |</p>
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<thead>
<tr>
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<tbody>
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<td>Oldham</td>
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<td>Tameside &amp; Glossop</td>
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<td>Trafford</td>
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<tr>
<td>Wigan Borough</td>
</tr>
</tbody>
</table>
CONTENTS

Policy Statement .......................................................................................................................................... 8
Equality & Equity Statement ......................................................................................................................... 8
Governance Arrangements ........................................................................................................................ 8
1. Introduction ............................................................................................................................................... 8
2. Definition ................................................................................................................................................ 9
3. Aims and Objectives ............................................................................................................................... 10
4. Criteria for Commissioning ................................................................................................................ 10
5. Description of Epidemiology and Need ............................................................................................... 11
6. Evidence Summary .............................................................................................................................. 11
7. Rationale behind the Policy Statement ................................................................................................. 11
8. Adherence to NICE Guidance ............................................................................................................ 11
9. Mechanism for Funding ......................................................................................................................... 12
10. Audit Requirements ............................................................................................................................. 12
11. Documents which have informed this Policy .................................................................................... 12
12. Links to other Policies .......................................................................................................................... 12
13. Date of Review ..................................................................................................................................... 13
14. Glossary ............................................................................................................................................... 13
References .................................................................................................................................................. 14
Appendix 1 – Evidence Review ................................................................................................................ 15
Policy Statement

Greater Manchester Shared Services (GMSS) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission ultrasound and pulsed electromagnetic systems for bone healing services in accordance with the criteria outlined in this document.

In creating this policy GMSS has 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.

Equality & Equity Statement

GMSS/CCG has 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. GMSS/CCG is 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, GMSS/CCG 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 GMSS 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 GMSS 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 Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

1. Introduction

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of ultrasound and pulsed electromagnetic systems for bone healing services by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available additional data on outcomes will be included in the review and the policy updated accordingly.

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.

2. Definition

What is it?

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 2 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 each day. It is intended to be used in the patient's home.

Pulsed electromagnetic field therapy

Pulsed electromagnetic field therapy, (the delivery of high intensity pulsed electric field (PEF) between 2 electrodes) also called pulsed magnetic therapy, pulse magnetotherapy, or PEMF, 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.
3. Aims and Objectives

**Aim**
This policy document aims to specify the conditions under which ultrasound and pulsed electromagnetic systems for bone healing will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

**Objectives**
- To reduce the variation in access to ultrasound and pulsed electromagnetic systems for bone healing.
- To ensure that ultrasound and pulsed electromagnetic systems for bone healing is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- To reduce unacceptable variation in the commissioning of ultrasound and pulsed electromagnetic systems for bone healing across Greater Manchester.
- To promote the cost-effective use of healthcare resources.

4. Criteria for Commissioning

**Mandatory Criteria**
Ultrasound bone healing systems are commissioned for patients who meet the following criteria:
- 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
- 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 Humorous 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

**Policy Exclusions**
Non orthopaedic applications of Pulsed electromagnetic field therapy are not covered by this policy

Clinicians can submit an Individual Funding Request (IFR) 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.
5. Description of 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.¹

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

6. Evidence Summary

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).

Full details of the Evidence Review are contained with Appendix 1.

7. 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.

8. Adherence to NICE Guidance

This policy adheres to most of the recommendations made in NICE MTG 12. 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 MTG 12 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.”

9. **Mechanism for Funding**

<table>
<thead>
<tr>
<th>Clinical Commissioning Group</th>
<th>Funding Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bury</td>
<td>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.</td>
</tr>
<tr>
<td>Bolton</td>
<td></td>
</tr>
<tr>
<td>Heywood, Middleton &amp; Rochdale</td>
<td></td>
</tr>
<tr>
<td>Manchester Central</td>
<td></td>
</tr>
<tr>
<td>Manchester North</td>
<td></td>
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<tr>
<td>Manchester South</td>
<td></td>
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<tr>
<td>Oldham</td>
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<tr>
<td>Salford</td>
<td></td>
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<tr>
<td>Stockport</td>
<td></td>
</tr>
<tr>
<td>Tameside &amp; Glossop</td>
<td></td>
</tr>
<tr>
<td>Trafford</td>
<td></td>
</tr>
<tr>
<td>Wigan</td>
<td></td>
</tr>
</tbody>
</table>

Individual Prior Approval should be sought prior to treatment from the Greater Manchester Shared Services 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 Humorous 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.

10. **Audit Requirements**

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

11. **Documents which have informed this Policy**

- Greater Manchester EUR Operational Policy

12. **Links to other Policies**

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).
13. Date of Review

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)

14. Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coupling gel</td>
<td>A colloid in which the solid disperse phase forms a network in combination with the fluid continuous phase, resulting in a viscous semi-rigid sol.</td>
</tr>
<tr>
<td>Electrodes</td>
<td>Conductors through which electricity enters or leaves an object, substance, or region.</td>
</tr>
<tr>
<td>Failed fusions</td>
<td>A situation in which a fracture fails to heal</td>
</tr>
<tr>
<td>Femur</td>
<td>The bone of the thigh articulating at the hip and the knee</td>
</tr>
<tr>
<td>Fibrous matrix</td>
<td>The intercellular substance of a tissue or the tissue from which a structure develops</td>
</tr>
<tr>
<td>Fibula</td>
<td>The outer and smaller of the two bones between the knee and the ankle</td>
</tr>
<tr>
<td>Fracture</td>
<td>A complete or incomplete break in a bone resulting from the application of excessive force.</td>
</tr>
<tr>
<td>Growth factors</td>
<td>A substance, such as a vitamin or hormone, which is required for the stimulation of growth in living cells.</td>
</tr>
<tr>
<td>Humerus</td>
<td>The bone of the upper arm forming joints at the shoulder and the elbow</td>
</tr>
<tr>
<td>Mineralised bone</td>
<td>Deposition of calcium, hydroxylapatite salts converting osteoid to rigid bone; dependent on mineral availability (calcium, phosphate and hydroxions), enzyme action (alkaline phosphatase), osteocyte activity (osteoblasts and osteoclasts), hormones (parathyroid hormone, thyroid calcitonin) and vitamin D.</td>
</tr>
<tr>
<td>MTG</td>
<td>Medical Technologies Guidance</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>Non-union</td>
<td>Complete failure of a break in the bone to heal</td>
</tr>
<tr>
<td>Proteins</td>
<td>A class of nitrogenous organic compounds which have large molecules composed of one or more long chains of amino acids.</td>
</tr>
<tr>
<td>Pseudarthrosis</td>
<td>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.</td>
</tr>
<tr>
<td>Pulsed electric field (PEF)</td>
<td>The delivery of high intensity pulsed electric field (PEF) between 2 electrodes, is a reparative technique most commonly used in the field of orthopedics.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<td>----------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Radius</td>
<td>The thicker and shorter of the two bones in the forearm jointed at the elbow and wrist.</td>
</tr>
<tr>
<td>Tibia</td>
<td>The inner and typically larger of the two bones between the knee and the ankle, parallel with the fibula.</td>
</tr>
<tr>
<td>Transducer</td>
<td>A device that converts variations in a physical quantity, such as pressure or brightness, into an electrical signal, or vice versa.</td>
</tr>
<tr>
<td>Ulna</td>
<td>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.</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>Sound or other vibrations having an ultrasonic frequency (a frequency above the upper limit of human hearing), particularly as used in medical imaging.</td>
</tr>
<tr>
<td>Union</td>
<td>Joining together</td>
</tr>
<tr>
<td>Vertebrae</td>
<td>The small bones forming the backbone</td>
</tr>
</tbody>
</table>

References

1. The relative incidence of fracture non-union in the Scottish population (5.17 million): a 5-year epidemiological study.
   Mills LA, Simpson AHRW.
## Appendix 1 – Evidence Review

**Title/Topic:** Ultrasound and pulsed electromagnetic systems for bone healing  
**Ref:** GM063

### Search Strategy

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

<table>
<thead>
<tr>
<th>Database</th>
<th>Result</th>
</tr>
</thead>
</table>
| NICE              | • NICE MTG 12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing  
• Nil for PEM                                                                                      |
| NHS Evidence      | • Cochrane review - cited below  
• York CRD - cited below  
• Cochrane database RCT - cited below  
• **Ultrasound and shockwave therapy for acute fractures in adults**  
Griffin XL, Parsons N, Costa ML, Metcalfe D.  
• Nil additional for ultrasound bone healing system                                                |
| SIGN              | Nil found                                                                                                                                                                                               |
| 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.  
• Nil additional for ultrasound bone healing system                                                |
| 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  
• Nil additional for ultrasound bone healing system                                                |
| 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) 12:477–484
  DOI 10.1007/s40258-014-0117-6

### 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.

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.

### The evidence

<table>
<thead>
<tr>
<th>Levels of evidence</th>
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</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
</tr>
<tr>
<td>Meta-analyses, systematic reviews of randomised controlled trials</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
</tr>
<tr>
<td>Randomised controlled trials</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
</tr>
<tr>
<td>Case-control or cohort studies</td>
</tr>
<tr>
<td><strong>Level 4</strong></td>
</tr>
<tr>
<td>Non-analytic studies e.g. case reports, case series</td>
</tr>
<tr>
<td><strong>Level 5</strong></td>
</tr>
<tr>
<td>Expert opinion</td>
</tr>
</tbody>
</table>
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](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.

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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
   

**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 after 3 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 ($I^2 = 58\%$). 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 ($I^2 = 57\%$). 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 $I^2$ 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 ($I^2=60\%$), 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.

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

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.

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.  

**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.
DRAFT

Greater Manchester EUR Policy Statement

Title/Topic: Facet Joint Injections for Back and Neck Pain
Reference: GM070
Date: November 2015
Under Section 4 Criteria for Commissioning the ‘Mandatory Criteria’ was amended to read as follows:

**Current Patients**

Facet Joint injections will continue to be commissioned for existing patients provided that there is a demonstrable improvement in quality of life measures following each treatment, this should be assessed using a validated research tool.

Treatments should only continue where alternative treatments such as analgesic medication are intolerable or produce undesirable side effects, such as unsteadiness in the elderly.

If treatment with facet joint injections are successful on more than two occasions suitable individuals should be referred for radiofrequency denervation if facet joint injections are to continue then the individual should be considered unsuitable for radiofrequency denervation including but not limited to:

- The presence of comorbidities that contraindicate radiofrequency denervation
- Access or other anticipated mechanical difficulties in the delivery of radiofrequency denervation
- Inability of the patient to adopt or maintain the required position for the safe delivery of radiofrequency denervation

Treatment is limited to no more than 2 injections a year the interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month intervals.

Facet joint injections should **not** be administered if:

- There is evidence of a local or systemic infection
- The patient is receiving substantial therapeutic or constitutional anticoagulation
- The patient is unwilling or is demonstrating a lack of cooperation

**Diagnostic Injections**

Facet joint injections are commissioned on monitored approval for patients being assessed for radiofrequency denervation in

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<td>16/09/2015</td>
<td>On the 16th September 2015 the Greater Manchester EUR Steering Group agreed the following changes to the policy:</td>
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line with the radiofrequency denervation policy only any other diagnostic use of facet joint injections will require an Individual Funding Request application.

**New Patients**

Facet joint injections are commissioned for patients who meet the following criteria:

- The back pain has been present for more than 1 year and all chronic pain management pathways have failed.

**AND**

- There is no other treatment option available for the patient

**OR**

- Alternative treatments such as analgesic medication are intolerable or produce undesirable side effects

**OR**

- The patient has demonstrated failure to respond to, or had a loss of response to other treatment options

**OR**

- Other treatment options are contraindicated and this is clearly documented

Wherever possible patients should be encouraged to:

- participate in mobilisation or rehabilitation therapy
- take effective pain relief medication
- where indicated (and where it is available) be referred for weight management support

---

**1.0 10/12/2015**

On the 18th November 2015 the GM EUR Steering Group approved the changes made to the policy on the 16th September 2015 and requested the following additional changes be made:

The order of the Mandatory Commissioning Criteria be changed to:-

1. New patients
2. Diagnostic injections
3. Current patients

With the following sentence being added under new patients:

*If new patients gain relief from facet joint injections and are suitable for radiofrequency denervation and have a positive response to facet joint injections they should be referred for radiofrequency denervation.*

The wording in Diagnostic Injections amended to read as follows:

*Facet joint injections are commissioned on Individual Prior Approval for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only, any other diagnostic use of facet joint injections will require an Individual Funding Request application. Patients given prior approval for two diagnostic injections will be conserved to have prior approval for radiofrequency*
| 15/03/2016 |  
|---|---|
| **denervation if the response to both injections is positive**  
With the following sentence being added for current patients -  
*All patients who are suitable for radiofrequency denervation should be referred after two successful facet joint injections.*  
**Funding Mechanism** updated to read as follows:-  
**New patients** – funding will be by individual prior approval (IPA) for 2 injections per year for patients meeting the mandatory criteria. Funding for other patients may be considered on an individual patient basis, if there is evidence of clinically exceptional circumstances.  
**Diagnostic facet joint injections** - Facet joint injections are commissioned on Individual Prior Approval (IPA) for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only. Any other diagnostic use of facet joint injections will require an Individual Funding Request application. Patients given prior approval for two diagnostic injections will be **conserved** to have prior approval for radiofrequency denervation if the response to both injections is positive.  
**Current patients** – funding will be by monitored approval but it will be expected that patients will have no more than 2 injections per year  
Post Consultation additional Evidence Review Summary Table as Appendix 2  
Subject to the above changes being made the GM EUR Steering Group approved the policy to be sent to through the governance process.  
Report updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.  
Wording for date of review amended to read “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)” on ‘Policy Statement’ and section ‘13. Date of Review’.  

| 7 & 14 | 23 | N/A | 6 & 14 |
### POLICY STATEMENT

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Wherever possible patients should be encouraged to:
- participate in mobilisation or rehabilitation therapy
- take effective pain relief medication
- where indicated (and where it is available) be referred for weight management support

If new patients gain relief from facet joint injections and are suitable for radiofrequency denervation and have a positive response to facet joint injections they should be referred for radiofrequency denervation.

### Diagnostic Injections

Facet joint injections are commissioned by Individual Prior Approval for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only, any other diagnostic use of facet joint injections will require an Individual Funding Request application. Patients given prior approval for two diagnostic injections will be conserved to have prior approval for radiofrequency denervation if the response to both injections is positive.

### Current Patients

Facet joint injections will continue to be commissioned for existing patients via monitored approval provided that there is a demonstrable improvement in quality of life measures following each treatment, this should be
assessed using a validated research tool.

Treatments should only continue where alternative treatments such as analgesic medication are intolerable or produce undesirable side effects, such as unsteadiness in the elderly.

If treatment with facet joint injections is successful on more than two occasions suitable individuals should be referred for radiofrequency denervation if facet joint injections are to continue then the individual should be considered unsuitable for radiofrequency denervation including but not limited to:

- The presence of comorbidities that contraindicate radiofrequency denervation
- Access or other anticipated mechanical difficulties in the delivery of radiofrequency denervation
- Inability of the patient to adopt or maintain the required position for the safe delivery of radiofrequency denervation

Treatment is limited to no more than 2 injections a year the interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month intervals.

Facet joint injections should not be administered if:

- There is evidence of a local or systemic infection
- The patient is receiving substantial therapeutic or constitutional anticoagulation
- The patient is unwilling or is demonstrating a lack of cooperation

**Policy Exclusions**

Facet joint injections for back and neck pain as part of a locally agreed pathway of care are excluded from this policy.

Facet joint injections for back and neck pain administered as part of a pre-agreed and funded trial are excluded from this policy.

**See Section 4: Criteria for Commissioning**

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<td>Greater Manchester Shared Services Effective Use of Resources Policy Team</td>
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Current patients – funding will be by monitored approval but it will be expected that patients will have no more than 2 injections per year.

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</table>
CONTENTS

Policy Statement .................................................................................................................................... 10
Equality & Equity Statement ................................................................................................................... 10
Governance Arrangements ..................................................................................................................... 10
1. Introduction .................................................................................................................................. 10
2. Definition ...................................................................................................................................... 11
3. Aims and Objectives .................................................................................................................... 11
4. Criteria for Commissioning ........................................................................................................... 11
5. Description of Epidemiology and Need ........................................................................................ 13
6. Evidence Summary ....................................................................................................................... 13
7. Rationale behind the Policy Statement .......................................................................................... 13
8. Adherence to NICE Guidance ...................................................................................................... 14
9. Mechanism for Funding ................................................................................................................ 14
10. Audit Requirements ..................................................................................................................... 14
11. Documents which have informed this Policy ............................................................................... 14
12. Links to other Policies .................................................................................................................. 14
13. Date of Review ............................................................................................................................ 14
14. Glossary ...................................................................................................................................... 15
References ............................................................................................................................................. 15
Appendix 1 – Evidence Review .............................................................................................................. 16
Policy Statement

Greater Manchester Shared Services (GMSS) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission facet joint injections for back and neck pain services in accordance with the criteria outlined in this document.

In creating this policy GMSS has 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.

Equality & Equity Statement

GMSS/CCG has 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. GMSS/CCG is 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, GMSS/CCG 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 GMSS 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 GMSS 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 Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

1. Introduction

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of facet joint injections for back and neck pain services by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available additional data on outcomes will be included in the review and the policy updated accordingly.

Facet joints are the small joints located between each vertebra that provide the spine with both stability and flexibility. Facet joint injections combine a local anaesthetic and a corticosteroid anti-inflammatory medication. Initially, a local anaesthetic is applied, then a small spinal needle is inserted into the facet joint, and anaesthetic and medication are injected using fluoroscopic (x-ray) guidance.
The evidence of effectiveness for facet joint injections for back and neck pain is equivocal at present and further high quality studies are needed to determine its effectiveness. This policy complies with the advice in NICE CG88 (Low back pain: Early management of persistent non-specific low back pain) and as a result facet joint injections for back and neck pain are not routinely commissioned. Use of these therapies should be within a recognised trial or a locally agreed care pathway.

2. Definition

Facet joint injections combine a local anaesthetic and a corticosteroid anti-inflammatory medication. The treatment is injected (the forcing of a liquid into a part) into the facet joint (the sliding joints allowing the vertebrae of the spine to glide over one another without losing contact) with the intent to alleviate chronic pain in that joint.

Back pain is a common problem that affects most people at some point in their life. It may be triggered by bad posture while sitting or standing, bending awkwardly, or lifting incorrectly. It’s not generally caused by a serious condition. In most cases, back pain will improve in a few weeks or months, although some people experience long-term pain or pain that keeps coming back.

3. Aims and Objectives

Aim
This policy document aims to specify the conditions under which facet joint injections for back and neck pain will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

Objectives
- To reduce the variation in access to facet joint injections for back and neck pain.
- To ensure that facet joint injections for back and neck pain is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- To reduce unacceptable variation in the commissioning of facet joint injections for back and neck pain across Greater Manchester.
- To promote the cost-effective use of healthcare resources.

4. Criteria for Commissioning

Mandatory Criteria

New Patients
Facet Joint injections are commissioned by Individual Prior Approval for patients who meet the following criteria:
- The back pain has been present for more than 1 year and all chronic pain management pathways have failed.
  AND
- There is no other treatment option available for the patient
  OR
- Alternative treatments such as analgesic medication are intolerable or produce undesirable side effects
  OR
- The patient has demonstrated failure to respond to, or had a loss of response to other treatment options
  OR

GM Facet Joint Injections for Back and Neck Pain Policy v1.0 Page 11 of 22
• Other treatment options are contraindicated and this is clearly documented

Wherever possible patients should be encouraged to:
• participate in mobilisation or rehabilitation therapy
• take effective pain relief medication
• where indicated (and where it is available) be referred for weight management support

If new patients gain relief from facet joint injections and are suitable for radiofrequency denervation and have a positive response to facet joint injections they should be referred for radiofrequency denervation.

Diagnostic Injections
Facet joint injections are commissioned by Individual Prior Approval (IPA) for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only, any other diagnostic use of facet joint injections will require an Individual Funding Request application. Patients given prior approval for two diagnostic injections will be conserved to have prior approval for radiofrequency denervation if the response to both injections is positive.

Current Patients
Facet joint injections will continue to be commissioned for existing patients by monitored approval provided that there is a demonstrable improvement in quality of life measures following each treatment, this should be assessed using a validated research tool.

Treatments should only continue where alternative treatments such as analgesic medication are intolerable or produce undesirable side effects, such as unsteadiness in the elderly.

If treatment with facet joint injections is successful on more than two occasions suitable individuals should be referred for radiofrequency denervation if facet joint injections are to continue then the individual should be considered unsuitable for radiofrequency denervation including but not limited to:
• The presence of comorbidities that contraindicate radiofrequency denervation
• Access or other anticipated mechanical difficulties in the delivery of radiofrequency denervation
• Inability of the patient to adopt or maintain the required position for the safe delivery of radiofrequency denervation

Treatment is limited to no more than 2 injections a year the interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month intervals.

Facet joint injections should not be administered if:
• There is evidence of a local or systemic infection
• The patient is receiving substantial therapeutic or constitutional anticoagulation
• The patient is unwilling or is demonstrating a lack of cooperation

All patients who are suitable for radiofrequency denervation should be referred after two successful facet joint injections

Policy Exclusions
Facet joint injections for back and neck pain as part of a locally agreed pathway of care are excluded from this policy.

Facet joint injections for back and neck pain administered as part of a pre-agreed and funded trial are excluded from this policy.
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.

5. Description of Epidemiology and Need

**Neck pain**

Neck pain is one of the most common musculoskeletal complaints. About two thirds of the population will experience neck pain at some point in their lives. Women are affected almost twice as much as men. Prevalence rises with age for men and women and is the highest in the age group between 50-59 years. The incidence of neck pain in general practice has been estimated to be between 18 and 23 per 1,000 registered patients per year. The percentage of people in whom neck pain becomes chronic is generally thought to be about 10%.

**Back pain**

Back pain is extremely common. 60-80% of people in the UK report back pain at some time in their lives. Low back pain has an estimated lifetime prevalence of 84% worldwide. The worldwide prevalence of chronic low back pain is about 23%. Simple back pain tends to affect those between 30 and 60 years of age, starting between 30 and 50. First onset outside this range should arouse suspicion of a sinister cause. Back pain is second only to the common cold as a cause of lost days at work. In 2005 the Trades Union Congress (TUC) estimated that 4.9 million working days per year are lost due to back pain. Research by the British Chiropractic Association found that 48% of people in Britain suffer from back or neck pain at any one time, possibly associated with spending an increasing amount of time seated at office desks. Highly demanding jobs, prolonged standing and awkward lifting are the most consistent factors predisposing to low back pain. A systematic review did not identify occupational carrying as an independent risk factor. Psychosocial work-related stress is an associated factor. Genetics may play a part. Smoking and obesity increase risk.

6. Evidence Summary

All of the evidence reviews felt that the level of evidence and consistency in findings was insufficient to show that facet joint injections for back pain were effective treatments. NICE CG88 recommends that this therapy is not routinely offered for back pain.

Full details of the Evidence Review are contained with Appendix 1.

7. Rationale behind the Policy Statement

NICE guidance and other systematic reviews have highlighted the lack of evidence of effectiveness for this procedure for back and neck pain. In light of this evidence Facet joint injections for back and neck pain are considered to be an unproven therapy and therefore is not routinely commissioned.
8. Adherence to NICE Guidance

This policy adheres fully to the recommendations made in NICE CG 88 – “Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomised controlled trials give conflicting evidence. Robust trials, including health economic evaluations, should be carried out to determine the effectiveness and cost effectiveness of invasive procedures – in particular, facet joint injections.”

9. Mechanism for Funding

<table>
<thead>
<tr>
<th>Clinical Commissioning Group</th>
<th>Funding Mechanism</th>
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<tbody>
<tr>
<td>Bury</td>
<td>TBA</td>
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<tr>
<td>Bolton</td>
<td></td>
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<tr>
<td>Heywood, Middleton &amp; Rochdale</td>
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<td>Manchester Central</td>
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<td>Manchester North</td>
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<td>Manchester South</td>
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<td>Oldham</td>
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<td>Salford</td>
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<td>Stockport</td>
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<td>Tameside &amp; Glossop</td>
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<td>Trafford</td>
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<td>Wigan</td>
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</table>

**New patients** – funding will be by individual prior approval (IPA) for 2 injections per year for patients meeting the mandatory criteria. Funding for other patients may be considered on an individual patient basis, if there is evidence of clinically exceptional circumstances.

**Diagnostic facet joint injections** - Facet joint injections are commissioned on Individual Prior Approval (IPA) for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only. Any other diagnostic use of facet joint injections will require an Individual Funding Request application. Patients given prior approval for two diagnostic injections will be **conserved** to have prior approval for radiofrequency denervation if the response to both injections is positive.

**Current patients** – funding will be by monitored approval but it will be expected that patients will have no more than 2 injections per year.

10. Audit Requirements

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

11. Documents which have informed this Policy

- Greater Manchester EUR Operational Policy

12. Links to other Policies

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).

13. Date of Review

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).
## 14. Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-inflammatory</td>
<td>Used to reduce inflammation (a localized physical condition in which part of the body becomes reddened, swollen, hot, and often painful, especially as a reaction to injury or infection).</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>A system of complementary medicine based on the diagnosis and manipulative treatment of misalignments of the joints, especially those of the spinal column.</td>
</tr>
<tr>
<td>Chronic</td>
<td>Persisting for a long time or constantly recurring.</td>
</tr>
<tr>
<td>Corticosteroid</td>
<td>Any of a group of steroid hormones produced in the adrenal cortex or made synthetically. There are two kinds: glucocorticoids and mineralocorticoids. They have various metabolic functions and some are used to treat inflammation.</td>
</tr>
<tr>
<td>Facet joints</td>
<td>The sliding joints allowing the vertebrae of the spine to glide over one another without losing contact.</td>
</tr>
<tr>
<td>Fluoroscopic (x-ray)</td>
<td>An imaging technique that uses X-rays to obtain real-time moving images of the interior of an object.</td>
</tr>
<tr>
<td>Local anaesthetic</td>
<td>An anaesthetic that affects a restricted area of the body.</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Relating to or denoting the musculature and skeleton together.</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NICE CG</td>
<td>NICE Clinical Guidance</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>Relating to the interrelation of social factors and individual thought and behavior.</td>
</tr>
<tr>
<td>Spinal needle</td>
<td>A needle specially designed for used in spinal injections.</td>
</tr>
<tr>
<td>Vertebra</td>
<td>Each of the series of small bones forming the backbone, having several projections for articulation and muscle attachment, and a hole through which the spinal cord passes</td>
</tr>
</tbody>
</table>

### References

1. Patient articles on Patient.co.uk on the epidemiology of back and neck pain
## Appendix 1 – Evidence Review

**Title/Topic:** Facet Joint Injections for Back and Neck Pain  
**Ref:** GM070

### Search Strategy

<table>
<thead>
<tr>
<th>Database</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICE</td>
<td>CG88 Low back pain: Early management of persistent non-specific low back pain – 1.6.2 “Do not offer injections of therapeutic substances into the back for non-specific low back pain”</td>
</tr>
<tr>
<td>NHS Evidence and NICE CKS</td>
<td>NICE guidance and systematic reviews cited below</td>
</tr>
<tr>
<td>SIGN</td>
<td>Nil found</td>
</tr>
<tr>
<td>Cochrane</td>
<td>Injection therapy for subacute and chronic low-back pain</td>
</tr>
<tr>
<td></td>
<td>Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P.</td>
</tr>
<tr>
<td>York</td>
<td>Systematic review of diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: an update</td>
</tr>
<tr>
<td></td>
<td>Sehgal N, Dunbar EE, Shah RV, Colson J</td>
</tr>
<tr>
<td>BMJ Clinical Evidence</td>
<td>BMJ Clinical Evidence review: Low back pain (chronic: Facet Joint Injections)</td>
</tr>
<tr>
<td></td>
<td>Roger Chou</td>
</tr>
<tr>
<td></td>
<td>Search date April 2009</td>
</tr>
<tr>
<td>BMJ Best Practice</td>
<td>Not done due to number of consistent reviews found</td>
</tr>
<tr>
<td>General Search (Google)</td>
<td>Not done due to number of consistent reviews found</td>
</tr>
<tr>
<td>Medline / Open Athens</td>
<td>Not done due to number of consistent reviews found</td>
</tr>
<tr>
<td>Other</td>
<td>Facet Joint Injection as a Diagnostic and Therapeutic Tool for Spinal Pain: A Review of Clinical and Cost Effectiveness</td>
</tr>
<tr>
<td></td>
<td>Canadian Agency for Drugs and Technology</td>
</tr>
<tr>
<td></td>
<td>Dianne Zakaria, PhD Becky Skidmore, BA(H), MLS March 2007</td>
</tr>
</tbody>
</table>

### Summary of the evidence

All of the evidence reviews felt that the level of evidence and consistency in findings was insufficient to show that facet joint injections for back pain were effective treatments. NICE CG88 recommends that this therapy is not routinely offered for back pain.

### The evidence

#### Levels of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Meta-analyses, systematic reviews of randomised controlled trials</td>
</tr>
<tr>
<td>Level 2</td>
<td>Randomised controlled trials</td>
</tr>
</tbody>
</table>
1. LEVEL 1: NICE GUIDANCE
CG88 Low back pain: Early management of persistent non-specific low back pain
May 2009

RESEARCH RECOMMENDATIONS

4.5 Invasive procedures
What is the effectiveness and cost-effectiveness of facet joint injections and radiofrequency lesioning for people with persistent non-specific low back pain?

Why this is important
Many invasive procedures are performed on people with persistent non-specific low back pain. These are usually undertaken after the condition has lasted a long time (more than 12 months). Procedures such as facet joint injections and radiofrequency lesioning are performed regularly in specialist pain clinics. There is evidence that pain arising from the facet joints can be a cause of low back pain, but the role of specific therapeutic interventions remains unclear. Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomised controlled trials give conflicting evidence.

Robust trials, including health economic evaluations, should be carried out to determine the effectiveness and cost effectiveness of invasive procedures – in particular, facet joint injections and radiofrequency lesioning. These should include the development of specific criteria for patient selection and a comparison with non-invasive therapies

2. LEVEL 1: SYSTEMATIC REVIEW
Facet Joint Injection as a Diagnostic and Therapeutic Tool for Spinal Pain: A Review of Clinical and Cost Effectiveness
Canadian Agency for Drugs and Technology
Dianne Zakaria, PhD Becky Skidmore, BA(H), MLS March 2007

Conclusions and Implications for Research and Policy
Ideally, all health care practices should be evidence-based. Because FJIs are costly, invasive procedures with associated risks and xray exposure, the importance of this requisite is magnified. According to the RCTs completed to date, FJIs with local anaesthetics or steroids have not been proven to be superior to placebo for the treatment of chronic LBP. Steroid FJIs have not been proven to be superior to local anaesthetic FJIs in the treatment of chronic neck pain secondary to a motor vehicle accident. The studies are limited. The most common limitation was the lack of appropriate diagnostic procedures to identify patients with pain of FJ origin. Only Barnsley et al.17 executed comparative-controlled FJ medial nerve branch blocks to identify an appropriate patient group before randomization. Future RCTs should:

- execute appropriate diagnostic procedures to identify patients with pain of FJ origin before randomization
- include adequate sample sizes based on a priori sample size calculations
- use a standardized treatment, with information about any concurrent treatment clearly stated
- establish the efficacy of FJIs relative to placebo before comparing medications with each other
• have an adequate follow-up duration of at least 12 months to ascertain long-term effects
• acknowledge basic study quality criteria such as concealment of allocation, baseline comparability of groups, blinding, documentation of loss to follow-up, and intention to treat analysis
• include economic evaluations to provide needed information about the costs of observed effects relative to alternative interventions.

Although FJIs have not been proven to be efficacious for the treatment of chronic LBP or chronic neck pain secondary to a motor vehicle accident, placebo- or comparative-controlled FJIs or medial nerve branch blocks are the standard for diagnosing pain of FJ origin. Unequivocally effective treatments with long term impacts remain elusive. In the meantime, guidelines have been developed for more judicious therapeutic use of FJIs on a case by case basis. It has been recommended that FJIs be used to facilitate other forms of active conservative treatment, such as physical exercise, rather than as a stand-alone pain treatment. Although Mayer et al. did not find FJIs with local anaesthetics and steroids to be an effective addition to exercise alone, the study groups did not consist of patients with confirmed pain of FJ origin. Using bone scintigraphy with SPECT to identify appropriate patients and target FJIs may offer a less burdensome and more cost-effective approach to management. More research is needed to evaluate this technology.

3. LEVEL 1: SYSTEMATIC REVIEW
Injection therapy for subacute and chronic low-back pain
Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P.

ABSTRACT

Background: The effectiveness of injection therapy for low-back pain is still debatable. Heterogeneity of target tissue, pharmacological agent and dosage generally found in randomized controlled trials (RCTs) points to the need for clinically valid comparisons in a literature synthesis.

Objectives: To determine if injection therapy is more effective than placebo or other treatments for patients with subacute or chronic low-back pain.

Search methods: We updated the search of the earlier systematic review and searched the Cochrane Central Register of Controlled Trials, MEDLINE and EMBASE databases from January 1999 to March 2007 for relevant trials reported in English, French, German, Dutch and Nordic languages. We also screened references from trials identified.

Selection criteria: RCTs on the effects of injection therapy involving epidural, facet or local sites for subacute or chronic low-back pain were included. Studies which compared the effects of intradiscal injections, prolotherapy or Ozone therapy with other treatments, were excluded unless injection therapy with another pharmaceutical agent (no placebo treatment) was part of one of the treatment arms. Studies about injections in sacroiliac joints and studies evaluating the effects of epidural steroids for radicular pain were also excluded.

Data collection and analysis: Two review authors independently assessed the quality of the trials. If study data were clinically and statistically too heterogeneous to perform a meta-analysis, we used a best evidence synthesis to summarize the results. The evidence was classified into five levels (strong, moderate, limited, conflicting or no evidence), taking into account the methodological quality of the studies.

Main results: 18 trials (1179 participants) were included in this updated review. The injection sites varied from epidural sites and facet joints (i.e. intra-articular injections, peri-articular injections and nerve
blocks) to local sites (i.e. tender- and trigger points). The drugs that were studied consisted of corticosteroids, local anesthetics and a variety of other drugs. The methodological quality of the trials was limited with 10 out of 18 trials rated as having a high methodological quality. Statistical pooling was not possible due to clinical heterogeneity in the trials. Overall, the results indicated that there is no strong evidence for or against the use of any type of injection therapy.

**Authors' conclusions:** There is insufficient evidence to support the use of injection therapy in subacute and chronic low-back pain. However, it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

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**4. LEVEL N/A: WEB GUIDANCE**

**BMJ Clinical Evidence review: Low back pain (chronic: Facet Joint Injections**

Roger Chou

Search date April 2009

**SUMMARY**

**Symptom improvement**

*Facet joint injections compared with placebo.* We don't know whether facet joint injections are more effective at decreasing pain in people with chronic low back pain (very low-quality evidence).

**Functional improvement**

*Corticosteroid injections compared with saline injections.* We don't know whether corticosteroid injections are more effective at improving disability at 1 and 3 months in people with chronic low back pain (very low-quality evidence).

**BENEFITS**

**Facet joint injection versus placebo:**

We found two systematic reviews (search dates 2008 and 2007). The reviews both reported the same two RCTs, neither review pooled data owing to heterogeneity between trials, and both reported that the first RCT is of high quality, and the second RCT is of low quality.

The first RCT included in both reviews (101 people with chronic low back pain without sciatica, with positive response to an uncontrolled facet joint block, see comment below) found no significant difference in pain relief and disability between corticosteroid and saline injections after 1 and 3 months (1 month: RR 0.89, 95% CI 0.65 to 1.21; 3 months: RR 0.90, 95% CI 0.69 to 1.17). Although a significantly higher proportion of people in the corticosteroid-injection group experienced marked or very marked improvement in pain relief after 6 months (46% with corticosteroid v 15% with placebo; P = 0.002), half of the people in the corticosteroid-injection group with positive results at 6 months experienced no benefits at earlier time periods, and differences were attenuated after controlling for increased use of co-interventions in the corticosteroid-injection group.

The second RCT included in both reviews (109 people with chronic low back pain based on clinical criteria, positive response to diagnostic facet joint block not required, see comment below) compared corticosteroids injected intra-articularly versus corticosteroids injected peri-capsularly versus placebo injections. No significant differences were reported between the groups for pain, disability, and work attendance at 1 hour, 2 weeks, 6 weeks, and 3 months (reported as not significant; P value not reported).

**HARMS**

The reviews reported that adverse effects such as headache, dizziness, transient local pain, tingling and numbness, and nausea were reported in small numbers of people (no further data reported).
COMMENT

Two other RCTs identified by the review did not distinguish between acute and chronic pain, and involved people with sciatica, so these RCTs have not been included here. The RCTs included in both reviews included people with pain arising from the facet joints. This is likely to indicate a definitive diagnosis for the source of low back pain.

5. LEVEL N/A: POOR QUALITY SYSTEMATIC REVIEW

Systematic review of diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: an update
Sehgal N, Dunbar EE, Shah RV, Colson J

CRD summary: This review concluded that local anaesthetic blocks of facet joints were reproducible, accurate and safe. The results presented did not appear to provide data on the reproducibility of facet joint blocks and the only data provided on accuracy related to false-positive rates, which seemed very high. The conclusions are therefore not supported by the data presented.

Authors' objectives: To evaluate the utility of facet joint block injections for the diagnosis of chronic spinal pain.

Searching: PubMed, EMBASE and CINAHL were searched from October 2004 to December 2006. In addition, the references of systematic and narrative reviews were screened for additional studies. The search terms were reported. The studies identified by these update searches were added to those identified by the previous review, which had been published in 2005 (see Other Publications of Related Interest).

STUDY SELECTION

Study designs of evaluations included in the review: Prospective and retrospective studies were eligible for inclusion. Case reports and reviews were excluded. The included studies were randomised controlled trials and prospective and retrospective studies.

Specific interventions included in the review: Studies that assessed diagnostic facet joint procedures that involved fluoroscopically/image-guided injections and controlled for false-positive responses (used comparative control or placebo control blocks) were eligible for inclusion. Studies that described injection techniques or ultrasound-guided infections were excluded, as were papers on therapeutic facet joint procedures.

Reference standard test against which the new test was compared: The reference standard for the diagnosis of zygapophysial facet joint pain was at least 50% pain relief for duration of the anaesthetic effect.

Participants included in the review: Studies of patients with spinal pain of greater than 3 months' duration were eligible for inclusion. Anatomical/cadaver studies were excluded.

Outcomes assessed in the review: No inclusion criteria relating to the outcomes were reported. The outcomes reported in the review were the prevalence of facet joint pain as a source of chronic spinal pain and false-positive rates.

How were decisions on the relevance of primary studies made? The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality: Two clinical reviewers assessed the studies for methodological quality using the AHRQ (Agency for Healthcare Research and Quality) criteria for diagnostic studies and the
QUADAS (Quality Assessment of Diagnostic Accuracy Studies) criteria. Studies had to fulfil at least 3 of the 5 AHRQ criteria and 7 of the 14 QUADAS criteria to be included in the review. The results of the quality assessment were reported as scores.

**Data extraction:** The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

**METHODS OF SYNTHESIS**

**How were the studies combined?** There were no details of the methods used to synthesise the results and a narrative synthesis was presented. The results of the individual studies were summarised.

**How were differences between studies investigated?** Differences between the studies were not formally investigated. The results of the individual studies were grouped according to region of the back assessed.

**Results of the review:** Two studies were identified by the current searches. These were added to the 37 studies identified for the previous review, giving a total of 39 included studies (total number of participants unclear). Cervical region (8 studies, 1,002 patients). Prevalence of facet joint pain was reported in 7 studies and ranged from 36 to 67%. The false-positive rate, which was reported in 5 studies, ranged from 27 to 63%. AHRQ scores ranged from 3 to 4 out of 5; QUADAS scores ranged from 7 to 13 out of 14. Thoracic region (3 studies, 183 patients). Prevalence of facet joint pain ranged from 34 to 48%. The false-positive rate ranged from 42 to 58%. All studies scored 3 out of 5 on the AHRQ criteria; QUADAS scores ranged from 9 to 11 out of 14. Lumbar region (15 studies, 2,572 patients). Prevalence of facet joint pain ranged from 14 to 52%. The false-positive rate, which was reported in 13 studies, ranged from 17 to 50%. AHRQ scores ranged from 3 to 4 out of 5 and 1 study appeared to score 1 out of 4; QUADAS scores ranged from 7 to 12 out of 14. One study reported a case of transient paraplegia after a cervical facet joint injection. Another reported a vasovagal episode and a short duration procedure-related discomfort. Seven other studies reported other complications with infection and bleeding.

**Authors’ conclusions:** Controlled, comparative, local anaesthetic blocks of facet joints are reproducible, accurate and safe.

**CRD commentary:** This review addressed a focused question that was supported by defined inclusion criteria. The literature search was limited to three databases over a 2-year period but, given that this was an update of a previous review, the date restrictions were appropriate. No attempts were made to locate unpublished studies so the review may be subject to publication bias. A detailed quality assessment was conducted, but the results of this were expressed as summary quality scores with no discussion of the individual quality items. The validity of the primary studies therefore remains unclear. Some details of a sample of the included studies were reported in the tables, but these did not provide sufficient information on the primary studies for the reader to judge their similarity and clinical relevance, and for some studies no details were provided; this makes it very difficult to interpret the results of the review. A narrative synthesis was presented but this was confusing and did not appear to address all of the included studies. Given the types of studies included it might have been more appropriate to conduct some form of statistical analysis; however, given the very limited details provided on the included studies it is difficult to assess this. The results presented did not appear to provide data on the reproducibility of facet joint blocks and the only data provided on accuracy related to false positive rates, which appeared very high. The authors’ conclusions are therefore not supported by the data presented, and the lack of data relating to the included studies makes the results of the review almost impossible to interpret.
Appendix 2 – Post Consultation additional Evidence Review Summary Table

Title/Topic: Facet Joint Injections for Back and Neck Pain
Ref: GM070
Greater Manchester EUR Policy Statement

Title/Topic: Radiofrequency Denervation for Back and Neck Pain
Reference: GM004
Date: November 2015
Under section 4 Criteria for Commissioning the Mandatory Criteria was updated to read as follows:-

Radiofrequency Denervation is commissioned if the provider is using Thermo-coagulation Radiofrequency Denervation and this is undertaken by experience clinicians using the correct technique within an environment suitable for delivery of this procedure and all appropriate back up is available. Pulsed Radiofrequency Denervation is not commissioned.

Radiofrequency Denervation is commissioned for individuals who meet the following criteria:

- there should be no other treatment option available for the patient

  OR

- alternative treatments such as analgesic medication are intolerable or produce undesirable side effects

  OR

- the patient has demonstrated failure to respond to, or had a loss of response to other treatment options

  OR

- Other treatment options are contraindicated and this is clearly documented

Prior to consideration for Radiofrequency Denervation the patient should:

- Have previously engaged with and complied with the advice / treatments advised by specialist pain management services

- Have a history of chronic, function-limiting pain of at least 12 months duration

- Show a good response to comparative double diagnostic blocks
  - consider Sacroiliac Joint Radiofrequency Denervation for patients who respond with at least 80% pain relief after fluoroscopy guided diagnostic sacroiliac joint injections
  - use the period of pain relief to rehabilitate the patient in close co-operation with other specialities

Patients should not have Radiofrequency Denervation if:

- they are pregnant or breast feeding

- there are any comorbidities present that contraindicate Radiofrequency Denervation
• they are unable to be positioned in the correct way prior to treatment

Following Radiofrequency Denervation and where clinically appropriate the patient should be referred for and participate in active rehabilitation.

In addition, wherever possible, patients should be encouraged to:
• participate in mobilisation or rehabilitation therapy
• take effective pain relief medication
• where indicated (and where it is available) be referred for weight management support

| 1.0 | 10/12/2015 | On the 18th November 2015 the GM EUR Steering Group approved the changes made to the policy on the 16th September 2015 and requested the following additional changes be made:

Clarity on what is meant by comparative double diagnostic blocks, added under the mandatory criteria section as follows:

Show a good response to comparative double diagnostic blocks (i.e. shows a good response to two consecutive diagnostic facet joint injections) NOTE: Patients who have had prior approval for double diagnostic blocks are considered to already have prior approval for Radiofrequency Denervation if the response to both injections is positive.

Repeat Radiofrequency Denervation criteria added to the Mandatory Criteria section of the policy as follows:

Patients requiring repeat Radiofrequency Denervation will need an application for prior approval with one of the following:
• where Radiofrequency Denervation has failed in the first instance - a clear statement as to why previous Radiofrequency Denervation failed and steps to be taken to avoid subsequent failure of Radiofrequency Denervation:
• where repeat Radiofrequency Denervation is needed due to nerve regeneration - a summary of the length of relief gained with an assurance that subsequent treatment is expected to gain similar results.

Funding Mechanism in the policy has been amended to read as follows:

Funding for Radiofrequency Denervation for neck and back pain will be Individual Prior Approval. Funding approval should be obtained via the Individual Funding Request route prior to referral.

Where Individual Prior Approval has already been given for 2 diagnostic facet joint injections in those cases individuals are already consider to have prior approval for Radiofrequency Denervation provided both injections gave a positive response.
Funding for other patients may be considered on an individual patient basis, if there is evidence of clinically exceptional circumstances.

Post Consultation additional Evidence Review Summary Table added as Appendix 2

Subject to the above amendments being made the GM EUR Steering Group approved the policy to go through the governance process.

Report updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.

Wording for date of review amended to read “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)” on ‘Policy Statement’ and section ‘13. Date of Review’.
### POLICY STATEMENT

<table>
<thead>
<tr>
<th>Title/Topic:</th>
<th>Radiofrequency denervation for back and neck pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue Date:</td>
<td>Insert Month and Year approved by AGG</td>
</tr>
</tbody>
</table>

#### Commissioning Recommendation:

Radiofrequency Denervation is commissioned if the provider is using Thermo-coagulation Radiofrequency Denervation and this is undertaken by experience clinicians using the correct technique within an environment suitable for delivery of this procedure and all appropriate back up is available. Pulsed Radiofrequency Denervation is **not** commissioned.

Radiofrequency Denervation is commissioned for individuals who meet the following criteria:

- there should be no other treatment option available for the patient
  - OR
- alternative treatments such as analgesic medication are intolerable or produce undesirable side effects
  - OR
- the patient has demonstrated failure to respond to, or had a loss of response to other treatment options
  - OR
- Other treatment options are contraindicated and this is clearly documented

Prior to consideration for Radiofrequency Denervation the patient should:

- Have previously engaged with and complied with the advice / treatments advised by specialist pain management services
- Have a history of chronic, function-limiting pain of at least 12 months duration
- Show a good response to comparative double diagnostic blocks
  - o consider Sacroiliac Joint Radiofrequency Denervation for patients who respond with at least 80% pain relief after fluoroscopy guided diagnostic sacroiliac joint injections
  - o use the period of pain relief to rehabilitate the patient in close cooperation with other specialities

Patients should **not** have Radiofrequency Denervation if:

- they are pregnant or breast feeding
- there are any comorbidities present that contraindicate Radiofrequency Denervation
- they are unable to be positioned in the correct way prior to treatment

Following Radiofrequency Denervation and where clinically appropriate the patient should be referred for and participate in active rehabilitation.

Continued…..

In addition, wherever possible, patients should be encouraged to:

- participate in mobilisation or rehabilitation therapy
• take effective pain relief medication
• where indicated (and where it is available) be referred for weight management support

See Section 4: Criteria for Commissioning

Date of Review: 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).

Prepared By: Greater Manchester Shared Services Effective Use of Resources Policy Team

<table>
<thead>
<tr>
<th>Approved By</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>Greater Manchester Effective Use of Resources Steering Group</td>
<td></td>
<td>GM EUR Steering Group recommended funding mechanism:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Funding for Radiofrequency Denervation for neck and back pain will be Individual Prior Approval. Funding approval should be obtained via the Individual Funding Request route prior to referral.</td>
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<td>Funding for other patients may be considered on an individual patient basis, if there is evidence of clinically exceptional circumstances.</td>
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<td>Greater Manchester Association Governing Group</td>
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<td>Central Manchester Clinical Commissioning Group</td>
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<td>Wigan Borough Clinical Commissioning Group</td>
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</table>
Policy Statement

Greater Manchester Shared Services (GMSS) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission Radiofrequency Denervation for back and neck pain services in accordance with the criteria outlined in this document.

In creating this policy GMSS has 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.

Equality & Equity Statement

GMSS/CCG has 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. GMSS/CCG is 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, GMSS/CCG 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 GMSS 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 GMSS 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.gmsscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

1. Introduction

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of Radiofrequency Denervation for back and neck pain services by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available additional data on outcomes will be included in the review and the policy updated accordingly.

Radiofrequency Denervation is a system using heat generated by radio waves targeted at specific nerves to temporarily interfere with their ability to transmit pain signals. The effectiveness of the treatment is not clear from the evidence available and further high quality studies are needed to determine its effectiveness. This policy complies with the advice in NICE CG88 and as a result
Radiofrequency Denervation for back and neck pain is not routinely commissioned. Use of this therapy should be within a recognised trial.

2. Definition

Back pain is a common problem that affects most people at some point in their life. It may be triggered by bad posture while sitting or standing, bending awkwardly, or lifting incorrectly. It is not generally caused by a serious condition. In most cases, back pain will improve in a few weeks or months, although some people experience long-term pain or pain that keeps coming back.

Neck pain or a stiff neck is a common problem and generally nothing to worry about. The pain and stiffness usually gets better after a few days or weeks, and is rarely a sign of a more serious problem. You can get a painful or stiff neck if you sleep in an awkward position, use a computer for a prolonged period of time, or strain a muscle because of bad posture. Anxiety and stress can also sometimes cause tension in your neck muscles, which can lead to pain in your neck.

Radiofrequency Denervation refers to a system that generates heat by radio waves that is used to target specific nerves and temporarily interfere with their ability to transmit pain signals.

3. Aims and Objectives

Aim

This policy document aims to specify the conditions under which Radiofrequency Denervation for back and neck pain will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

Objectives

- To reduce the variation in access to Radiofrequency Denervation for neck and back pain.
- To ensure that Radiofrequency Denervation for neck and back pain is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- To reduce unacceptable variation in the commissioning of Radiofrequency Denervation for neck and back pain across Greater Manchester.
- To promote the cost-effective use of healthcare resources.

4. Criteria for Commissioning

Mandatory Criteria

Radiofrequency Denervation is commissioned if the provider is using Thermo-coagulation Radiofrequency Denervation and this is undertaken by experienced clinicians using the correct technique within an environment suitable for delivery of this procedure and all appropriate back up is available. Pulsed Radiofrequency Denervation is not commissioned.

Radiofrequency Denervation is commissioned for individuals who meet the following criteria:

- there should be no other treatment option available for the patient
- alternative treatments such as analgesic medication are intolerable or produce undesirable side effects
- the patient has demonstrated failure to respond to, or had a loss of response to other treatment options
- Other treatment options are contraindicated and this is clearly documented
Prior to consideration for Radiofrequency Denervation the patient should:

- Have previously engaged with and complied with the advice / treatments advised by specialist pain management services
- Have a history of chronic, function-limiting pain of at least 12 months duration
- Show a good response to comparative double diagnostic blocks (i.e. shows a good response to two consecutive diagnostic facet joint injections) NOTE: Patients who have had prior approval for double diagnostic blocks are considered to already have prior approval for Radiofrequency Denervation if the response to both injections is positive.
  - consider Sacroiliac Joint Radiofrequency Denervation for patients who respond with at least 80% pain relief after fluoroscopy guided diagnostic sacroiliac joint injections
  - use the period of pain relief to rehabilitate the patient in close co-operation with other specialities

Patients should **not** have Radiofrequency Denervation if:

- they are pregnant or breast feeding
- there are any comorbidities present that contraindicate Radiofrequency Denervation
- they are unable to be positioned in the correct way prior to treatment

Following Radiofrequency Denervation and where clinically appropriate the patient should be referred for and participate in active rehabilitation.

In addition, wherever possible, patients should be encouraged to:

- participate in mobilisation or rehabilitation therapy
- take effective pain relief medication
- where indicated (and where it is available) be referred for weight management support

**Repeat Radiofrequency Denervation**

Patients requiring repeat Radiofrequency Denervation will need an application for prior approval with one of the following:

- where Radiofrequency Denervation has failed in the first instance - a clear statement as to why previous Radiofrequency Denervation failed and steps to be taken to avoid subsequent failure of Radiofrequency Denervation:
- where repeat Radiofrequency Denervation is needed due to nerve regeneration - a summary of the length of relief gained with an assurance that subsequent treatment is expected to gain similar results

**Policy Exclusions**

Radiofrequency Denervation for back and neck pain as part of a pre-agreed and funded trial is excluded from this policy.

Where a patient does not meet the criteria, but their clinical circumstances are deemed to be exceptional, funding will be made available on an individual patient basis. Individual Funding Requests should be made in line with the procedures described in the Greater Manchester EUR Operational Policy.

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.

5. **Description of Epidemiology and Need**

**Neck pain**

Neck pain is one of the most common musculoskeletal complaints. About two thirds of the population will experience neck pain at some point in their lives. Women are affected almost twice as much as men. Prevalence rises with age for men and women and is the highest in the age group between 50-59 years. The incidence of neck pain in general practice has been estimated to be between 18 and 23 per 1,000 registered patients per year. The percentage of people in whom neck pain becomes chronic is generally thought to be about 10%.

**Low Back pain**

Back pain is extremely common. 60-80% of people in the UK report back pain at some time in their lives. Low back pain has an estimated lifetime prevalence of 84% worldwide. The worldwide prevalence of chronic low back pain is about 23%. Simple back pain tends to affect those between 30 and 60 years of age, starting between 30 and 50. First onset outside this range should arouse suspicion of a sinister cause. Back pain is second only to the common cold as a cause of lost days at work. In 2005 the Trades Union Congress (TUC) estimated that 4.9 million working days per year are lost due to back pain. Research by the British Chiropractic Association found that 48% of people in Britain suffer from back or neck pain at any one time, possibly associated with spending an increasing amount of time seated at office desks. Highly demanding jobs, prolonged standing and awkward lifting are the most consistent factors predisposing to low back pain. A systematic review did not identify occupational carrying as an independent risk factor. Psychosocial work-related stress is an associated factor. Genetics may play a part. Smoking and obesity increase risk.

**Thoracic back pain**

Prevalence data ranged from 4.0-72.0% (at any one time), 0.5-51.4% (7-day), 1.4-34.8% (1-month), 4.8-7.0% (3-month), 3.5-34.8% (1-year) and 15.6-19.5% (lifetime). Studies reported a higher prevalence for thoracic back pain in children and adolescents, especially for females. In children and adolescents, thoracic back pain was associated with female gender, postural changes associated with backpack use, backpack weight, other musculoskeletal symptoms, participation in specific sports, chair height at school and difficulty with homework. Poorer mental health and age transition from early to late adolescence were also significant risk factors. In adults, thoracic back pain was associated with concurrent other musculoskeletal symptoms and difficulty in performing activities of daily living.

6. **Evidence Summary**

All of the evidence reviews felt that the level of evidence and consistency in findings was insufficient to show that Radiofrequency denervation for back and neck pain was an effective treatment. NICE CG88 (Low back pain: Early management of persistent non-specific low back pain) recommends that this therapy is not routinely offered for back and neck pain.

Full details of the Evidence Review are contained with Appendix 1.
7. **Rationale behind the Policy Statement**

NICE guidance and other systematic reviews have highlighted the lack of evidence of effectiveness for this procedure for back and neck pain. In light of this evidence radiofrequency facet joint denervation is considered to be an unproven therapy and therefore is not routinely commissioned.

8. **Adherence to NICE Guidance**

This policy adheres fully to the recommendations made in NICE CG88 (Low back pain: Early management of persistent non-specific low back pain) Section 1.9.4 “**Do not** refer people for radio frequency facet joint denervation”.

9. **Mechanism for Funding**

<table>
<thead>
<tr>
<th>Clinical Commissioning Group</th>
<th>Funding Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bury</td>
<td>Funding for Radiofrequency Denervation for back and neck pain will be Individual Prior Approval. Funding approval should be obtained via the IFR route prior to referral.</td>
</tr>
<tr>
<td>Bolton</td>
<td></td>
</tr>
<tr>
<td>Heywood, Middleton &amp; Rochdale</td>
<td>Where Individual Prior Approval has already been given for 2 diagnostic facet joint injections in those cases individuals are already consider to have prior approval for Radiofrequency Denervation provided both injections gave a positive response.</td>
</tr>
<tr>
<td>Manchester Central</td>
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<td>Manchester North</td>
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<td>Wigan</td>
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Funding for other patients may be considered on an individual patient basis, if there is evidence of clinically exceptional circumstances.

10. **Audit Requirements**

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

11. **Documents which have informed this Policy**

- Greater Manchester EUR Operational Policy

12. **Links to other Policies**

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).

13. **Date of Review**

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).

14. **Glossary**

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
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</thead>
<tbody>
<tr>
<td>Chiropractic</td>
<td>A system of complementary medicine based on the diagnosis and therapy</td>
</tr>
<tr>
<td><strong>Musculoskeletal</strong></td>
<td>Relating to or denoting the musculature and skeleton together</td>
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<td>---------------------</td>
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</tr>
<tr>
<td><strong>Nerves</strong></td>
<td>A whitish fibre or bundle of fibres in the body that transmits impulses of sensation to the brain or spinal cord, and impulses from these to the muscles and organs</td>
</tr>
<tr>
<td><strong>NICE</strong></td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td><strong>NICE CG</strong></td>
<td>NICE Clinical Guidance</td>
</tr>
<tr>
<td><strong>Pain signals</strong></td>
<td>Impulses varied in the nerve fibres that alert the brain to pain stimuli</td>
</tr>
<tr>
<td><strong>Postural</strong></td>
<td>Pertaining to the posture or position of the body, the attitude or carriage of the body as a whole, or the position of the limbs (the arms and legs)</td>
</tr>
<tr>
<td><strong>Psychosocial</strong></td>
<td>Relating to the interrelation of social factors and individual thought and behaviour</td>
</tr>
<tr>
<td><strong>Radio waves</strong></td>
<td>Electromagnetic waves of a frequency between about $10^4$ and $10^{11}$ or $10^{12}$ Hz, as used for long-distance communication</td>
</tr>
<tr>
<td><strong>Systematic Review</strong></td>
<td>A systematic review answers a defined research question by collecting and summarising all the available evidence that fits the pre-specified eligibility criteria of the review</td>
</tr>
<tr>
<td><strong>Thoracic</strong></td>
<td>Relating to the thorax (the part of the body of a mammal between the neck and the abdomen)</td>
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</tbody>
</table>

**References**

1. Patient articles on Patient.co.uk on the epidemiology of back and neck pain
Appendix 1 – Evidence Review

Radiofrequency Denervation for Back and Neck Pain
GM004

Search Strategy

<table>
<thead>
<tr>
<th>Database</th>
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<tr>
<td>NICE</td>
<td>CG88 Low back pain: Early management of persistent non-specific low back pain – “DO NOT USE”</td>
</tr>
<tr>
<td>NHS Evidence and NICE CKS</td>
<td>Studies found cited elsewhere in table</td>
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<tr>
<td>Sign</td>
<td>Nil found</td>
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<tr>
<td>Cochrane</td>
<td>Radiofrequency denervation for neck and back pain (Review) Niemisto L, Kalso EA, Malmivaara A, Seitсалo S, Hurri H</td>
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<tr>
<td>BMJ Clinical Evidence</td>
<td>BMJ Clinical Evidence review: Low back pain (chronic: Radiofrequency denervation Roger Chou Search date April 2009</td>
</tr>
<tr>
<td>BMJ Best Practice</td>
<td>BMJ Best Practice - Summary statement: Radiofrequency denervation (website – extract cited below)</td>
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<tr>
<td>General Search (Google)</td>
<td>Cochrane study cited above</td>
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<tr>
<td>Medline / Open Athens</td>
<td>Not done due to NICE statement</td>
</tr>
<tr>
<td>Other</td>
<td>Best Bets Website Review: Radiofrequency denervation for lumbar zygapophysial joint pain Report By: Simon Carley - Consultant in Emergency Medicine Institution: Manchester Royal Infirmary Date Submitted: 6th July 2005</td>
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</table>

Summary of the evidence

All of the evidence reviews felt that the level of evidence and consistency in findings was insufficient to show that Radiofrequency denervation for back and neck pain was an effective treatment. NICE CG88 recommends that this therapy is not routinely offered for back and neck pain.

The evidence

Levels of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>Level 1</td>
<td>Meta-analyses, systematic reviews of randomised controlled trials</td>
</tr>
<tr>
<td>Level 2</td>
<td>Randomised controlled trials</td>
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</table>
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**  
   CG88 Low back pain: Early management of persistent non-specific low back pain  
   May 2009  

**GUIDANCE**  
1.9.4 **Do not** refer people for any of the following procedures:  
   - intradiscal electrothermal therapy (IDET)  
   - percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)  
   - radiofrequency facet joint denervation.  

**RESEARCH RECOMMENDATIONS**  
4.5 Invasive procedures  
What is the effectiveness and cost-effectiveness of facet joint injections and radiofrequency lesioning for people with persistent non-specific low back pain?  

**Why this is important**  
Many invasive procedures are performed on people with persistent non-specific low back pain. These are usually undertaken after the condition has lasted a long time (more than 12 months). Procedures such as facet joint injections and radiofrequency lesioning are performed regularly in specialist pain clinics. There is evidence that pain arising from the facet joints can be a cause of low back pain, but the role of specific therapeutic interventions remains unclear. Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomised controlled trials give conflicting evidence.  

Robust trials, including health economic evaluations, should be carried out to determine the effectiveness and cost effectiveness of invasive procedures – in particular, facet joint injections and radiofrequency lesioning. These should include the development of specific criteria for patient selection and a comparison with non-invasive therapies.  

2. **LEVEL 1: SYSTEMATIC REVIEW**  
   BMJ Clinical Evidence review: Low back pain (chronic: Radiofrequency denervation  
   Roger Chou  
   Search date April 2009  

**SUMMARY**  
**Symptom improvement**  
Compared with sham treatment or placebo: We don't know whether radiofrequency denervation is more effective than placebo at reducing pain in people with presumed facet joint or discogenic low back pain (very low-quality evidence).  

**Functional improvement**  
Compared with sham treatment or placebo We don't know whether radiofrequency denervation is more effective at improving function in people with presumed facet joint or discogenic low back pain (very low-quality evidence).
BENEFITS

Radiofrequency denervation versus no treatment/sham treatment or usual care

We found one systematic review (search date 2008; 8 RCTs), which evaluated radiofrequency denervation for non-radiculolow back pain.

Six RCTs included in the review (322 people) evaluated radiofrequency denervation for presumed facet joint pain versus sham treatment, and one RCT (49 people) included in the review evaluated radiofrequency denervation for presumed discogenic back pain versus lidocaine injection.

Four RCTs of radiofrequency denervation for presumed facet joint pain were rated higher quality by the review.

The first higher-quality RCT included in the review (40 people selected by controlled facet joint blocks and an ablation technique believed to be optimal) found that radiofrequency denervation improved generalised, back, and leg pain compared with sham treatment at 6 months (0–10 visual analogue scale [VAS]: −1.4 points to −1.6 points), but the difference was not statistically significant for back pain (the main symptom thought to be associated with facet pain).

The review reported that baseline scores in the radiofrequency denervation group were on average 1.6 points higher, which suggests inadequate randomisation. The review reported that the other three higher-quality RCTs used uncontrolled diagnostic facet joint blocks to select the people included in the trials, and, may have used suboptimal ablation techniques, and all reported conflicting results.

The second higher-quality RCT (30 people) found that radiofrequency denervation moderately improved mean VAS pain and Oswestry Disability Index (ODI) scores through 2 months (pain: mean VAS score on a 0–10 VAS: −2.4 with radiofrequency v −0.4 with placebo; P <0.05; ODI: −11.1 with radiofrequency denervation v +1.7 with placebo; P <0.05).

The third higher-quality RCT (70 people) found radiofrequency denervation superior to sham treatment for mean improvement in Roland Morris Disability Questionnaire (RMDQ) scores at 4 weeks (RMDQ scores: −8.4 with radiofrequency denervation v −2.2 with placebo; P = 0.05), but there were no statistically significant differences in ODI or VAS pain scores between groups (reported as not significant; P value not reported). However, the RCT found no significant difference between groups for RMDQ score at 12 weeks.

The fourth higher-quality RCT (82 people) found no differences between radiofrequency denervation compared with sham treatment on any outcome (further data not reported).

The first lower-quality RCT included in the review (60 people) found that conventional but not pulsed radiofrequency denervation improved pain (VAS 0–10 scale: 0.8–1.5 points, significance not reported) and function (4–6 points on the ODI; significance not reported) compared with sham treatment at 1 year.

The review reported that the second lower-quality RCT had serious methodological shortcomings, including lack of intention-to-treat analysis, and therefore was not reported.

The one RCT included in the review (49 people) that evaluated radiofrequency for presumed discogenic pain (based on positive lumbar provocative discography) found that radiofrequency denervation of the ramus communicans nerves significantly improved pain, SF-36 bodily pain, and SF-36 physical function scores compared with lidocaine injection after 4 months (pain: mean VAS [0–10 scale] pain scores: 3.8 with radiofrequency denervation v 6.3 with lidocaine injection; P <0.05; SF-36 bodily pain: 44 with radiofrequency denervation v 32 with lidocaine injection; P <0.05; SF-36 physical function: 59 with radiofrequency denervation v 46 with lidocaine injection; P <0.05). The review reported that the RCT was of lower quality.
HARMS

Radiofrequency denervation versus no treatment/sham treatment or usual care

The review reported that one of the included RCTs found a case of mild, subjective, and transient lower limb weakness after radiofrequency denervation. The review included two other RCTs that found no difference in adverse effects between radiofrequency denervation compared with sham treatment, although radiofrequency denervation was associated with trends towards increased post-procedural pain.

COMMENT

The RCTs in the review included people with pain presumably arising from the facet joint or intervertebral disc. However, the accuracy of methods for identifying patients with facet joint or discogenic pain is unknown. RCTs of radiofrequency denervation for presumed facet joint pain are difficult to interpret because higher-quality studies reported conflicting studies, some RCTs may have used suboptimal techniques, and the only RCT to use controlled facet joint diagnostic blocks to select patients for inclusions reported baseline differences between the treatment and sham groups.

3. LEVEL 1: SYSTEMATIC REVIEW

Radiofrequency denervation for neck and back pain (Review)

Niemisto L, Kalso EA, Malmivaara A, Seitsalo S, Hurri H

Cochrane database of systematic review

ABSTRACT

Background: The diagnosis of cervical or lumbar zygapophyseal joint pain can only be made by using local anaesthesia to block the nerves supplying the painful joint. There is a lack of effective treatment for chronic zygapophyseal joint pain or discogenic pain. Radiofrequency denervation appears to be an emerging technology, with substantial variation in its use between countries.

Objectives: To assess the effectiveness of radiofrequency denervation for the treatment of musculoskeletal pain disorders.

Search methods: We searched MEDLINE, PsycLIT, and EMBASE from start to February 2002, plus the Cochrane Library 2002, Issue 2. The references of identified articles were checked and three experts in the field of radiofrequency treatment were consulted to identify studies we might have missed.

Selection criteria: Randomized controlled trials (RCTs) of radiofrequency denervation for musculoskeletal pain disorders, with no language or date restrictions.

Data collection and analysis: Two authors selected RCTs that met predefined inclusion criteria, extracted the data, and assessed the main results and methodological quality of the selected trials, using standardized forms. Qualitative analysis was conducted to evaluate the level of scientific evidence.

Main results: We found only nine articles, reporting on seven relevant RCTs. Six of the seven were considered to be high-quality. The selected trials included 275 randomized patients, 141 of whom received active treatment. One study examined cervical zygapophyseal joint pain, two cervicobrahial pain, three lumbar zygapophyseal joint pain, and one discogenic low-back pain. The study sample sizes were small, follow-up times short, and there were some deficiencies in patient selection, outcome assessments, and statistical analyses. The level of scientific evidence for the short-term effectiveness of radiofrequency denervation was limited for cervical zygapophyseal joint and cervicobrahial pain, and conflicting for lumbar zygapophyseal joint pain. There was limited evidence suggesting that intradiscal radiofrequency thermocoagulation was not effective for discogenic low-back pain.
Authors' conclusions: The selected trials provide limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain of zygapophyseal joint origin and for chronic cervicobrachial pain; conflicting evidence on the short-term effect of radiofrequency lesioning on pain and disability in chronic low-back pain of zygapophyseal joint origin; and limited evidence that intradiscal radiofrequency thermocoagulation is not effective for chronic discogenic low-back pain. There is a need for further high-quality RCTs with larger patient samples and data on long-term effects, for which current evidence is inconclusive. Furthermore, RCTs are needed in non-spinal indications where radiofrequency denervation is currently used without any scientific evidence.

4. LEVEL 1: SYSTEMATIC REVIEW
Radiofrequency denervation for facet joint low back pain: a systematic review
Poetscher AW, Gentil AF, Lenza M, Ferretti M.

ABSTRACT

Study Design: A systematic review and meta-analysis of randomized controlled trials.

Objective: To assess treatment effects (benefits and harms) of radiofrequency denervation for patients with facet joint-related chronic low back pain.

Summary of Background Data: There is no consensus regarding the treatment efficacy of facet joint radiofrequency denervation (FJRD) and how it compares with nerve blockades and joint infiltration with anesthetics and/or corticosteroids.

Methods: We searched the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and LILACS for randomized controlled trials that compared FJRD with blockades, infiltrations, or placebo. Primary outcomes were pain, functional status, and quality of life. Secondary outcomes were cost-effectiveness and complications.

Results: Fifteen studies were selected and 9 were eligible. Overall quality of evidence was rated low to moderate. The evidence favored FJRD regarding pain control. There was no sufficient evidence for cost-effectiveness and complications.

Conclusion: The available evidence reviewed in this study should be interpreted with caution. The data indicate that FJRD is more effective than placebo in pain control and functional improvement and is also possibly more effective than steroid injections in pain control. Complications and adverse effects were not sufficiently reported to allow comparisons, and there was no evidence for cost-effectiveness. High-quality randomized controlled trials addressing pain, function, quality of life, complications, and cost-effectiveness are urgently needed.

5. LEVEL 1: SYSTEMATIC REVIEW
Best Bets Website Review: Radiofrequency denervation for lumbar zygapophysial joint pain
Report By: Simon Carley - Consultant in Emergency Medicine
Institution: Manchester Royal Infirmary
Date Submitted: 6th July 2005

Three Part Question: [In patients with chronic low back pain of zygapophysial joint origin] is [radiofrequency denervation of medial lumbar nerves better than standard rehabilitation] at [improving pain and function]
**Clinical Scenario:** A 55 year old woman represents to her general practitioner with back pain of 3 years duration. Previous assessments and investigations have not suggested a serious cause of her back pain but it so severe that she has had to give up work and has become depressed. She attends as she has read on the internet that the nerves to the joints in the back can be electrified and that this will cure her pain. She asks you if this is true and if so could you refer her for the treatment.

**Search Strategy:** Medline 1966 - June 2005. OVID via ATHENS. [low back pain.mp. or exp Low Back Pain/ or back pain.mp. or exp Back Pain/ or lumbar pain.mp.] and [zygapophysial.mp. or exp Zygaphophyseal Joint/ or facet joint.mp.] and [radio$.mp. or radiofrequency.mp. or exp DENERVATION/ or denervation.mp.] limit to humans and english language and abstracts.

**Search Outcome:** Medline. 86 papers found of which one 2 recent high quality systematic reviews were found. In addition a recent clinical trial was identified.

**Relevant Paper(s)**

<table>
<thead>
<tr>
<th>Author, date and country</th>
<th>Patient group</th>
<th>Study type (level of evidence)</th>
<th>Outcomes</th>
<th>Key results</th>
<th>Study Weaknesses</th>
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<tbody>
<tr>
<td>Niemisto I 2003 Finland</td>
<td>Randomised controlled trials of radiofrequency denervation for neck and back pain. Identified through wide ranging search under the auspices of the Cochrane Collaboration.</td>
<td>Systematic review.</td>
<td>Number of papers found</td>
<td>7 RCTs were identified. 6 were high quality. 3 papers (including a total of 142 patients) specifically looked at lumbar zygapophysial pain.</td>
<td>Lack of consistent outcome measure in the included trials. Lack of placebo controlled diagnostic blocks may have led to an increased number of false positive included patients.</td>
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<td>Inclusion criteria in trials.</td>
<td>All were in chronic back pain. All patients in the lumbar trials had confirmatory diagnostic blocks before being considered for denervation.</td>
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<td>Principle results</td>
<td>One study showed a small decrease in short term pain (van Kleef), one showed a neutral effect and one was flawed due to a lack of intention to treat. There was conflicting evidence with regard to function scores. No formal meta-analysis was performed.</td>
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<tr>
<td>Slipman CW 2003 USA</td>
<td>Clinical trials of zygapophysial joint injections for patients with chronic back pain</td>
<td>Systematic review (without meta-analysis)</td>
<td>Number of papers found</td>
<td>15 studies were found, 4 were prospective trials included in this review. 2 were RCTs, one was a double blind controlled study and one was a case series.</td>
<td>Confirmatory blocks were usually single attempts and may have led to an increase in the number of false positive included patients.</td>
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<td>Patient characteristics</td>
<td>Trias included patients unresponsive to other therapies which means that there is a degree of inclusion bias. All patients had chronic back pain. All patients had a confirmatory diagnostic block prior to randomisation.</td>
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<td>Principle outcome measures</td>
<td>Pain: Conflicting results were found though there does appear to be a benefit in</td>
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</table>
Comment(s): Low back pain is one of the most common reasons for working age patients to suffer chronic pain, sickness and work loss. Studies have suggested that a significant proportion of patients with low back pain will have pain originating from the zygapophysial joints. A theoretically attractive therapeutic intervention is to ablate the medial lumbar nerves that supply the joint, thereby rendering it anaesthetic. In all these studies the presence of zygapophysial pain was confirmed using diagnostic blocks which is an essential precurser to any trial in this area. The two reviews, whilst assessing the same papers come to similar conclusions that there is evidence for a degree of pain relief in the short to medium term but that there is little evidence to suggest that this is match ed by an increase in function. The most recent trial contains no control group and is retrospective and therefore of little help in answering the question.

Clinical Bottom Line: In patients with confirmed zygapophysial joint pain radiofrequency ablation of medial lumbar nerves may provide short to medium term pain relief but is unlikely to result in a significantly increased functional capacity.

References
### Appendix 2 – Post Consultation additional Evidence Review Summary Table

**Title/Topic:** Radiofrequency Denervation for Neck and Back Pain  
**Ref:** GM004

<table>
<thead>
<tr>
<th>Evidence Type</th>
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<td>Evidence review summary</td>
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