

Use of an upright, standing or positional (open) MRI scanner

NHS Leeds Clinical Commissioning Group

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Target audience:	Primary and secondary care clinicians, individual funding request panels and the public
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1.0 Introduction

This policy is designed to clarify the agreements between NHS Leeds Clinical Commissioning Group (CCG) and providers regarding the commissioning of upright, standing or positional Magnetic Resonance Image (MRI) diagnostic scan.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below).

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks.

Providers will not be paid for any activity with regards this framework which has not been approved in advance.

2.0 Definitions

Upright, standing or positional MRI (uMRI) is a type of vertically, open MRI that has been developed in recent years. Such systems are open at the front and top, with the magnetic poles placed on either side of the patient and allow for vertical (upright, weight bearing), horizontal (recumbent) positioning, and dynamic kinetic flexion and extension manoeuvres.

Current uMRI scanners generally use medium field magnets of 0.5T or 0.6T, uMRI here refers to any system of 0.5T or greater that allows for scanning in various positions, regardless of manufacturer. By comparison, the most advanced standard rMRI scanners have magnet strength of at least 1.0T and up to 3.0T allowing for the greatest resolution generally in a shorter amount of time. With 0.6T magnets, uMRI requires more time to obtain images with lower resolution.

Slower imaging times with uMRI may create difficulty for patients who are unable to remain still while in a standing or sitting position; not comfortable secondary to pain; or are unstable in such positions. Longer exam times may also decrease the overall patient flow and volume of patients that can be accommodated.

The proposed advantages of uMRI are based on the ability to scan the spine (or joints) in different positions (including the position where clinical symptoms are more pronounced) and assess the effects of weight bearing, position and dynamic movement.

Commissioner – NHS Leeds CCG

Providers – any hospital/clinic/centre with a commissioning agreement with NHS Leeds CCG, (including NHS and independent sector providers).

Level 2 – Primary care

Level 3 – Extended primary care intermediate services

Level 4 – Hospital services

3.0 Commissioning position

<p><u>Not routinely commissioned</u></p>	<p>Standing, upright, weight-bearing or positional (open) MRI will NOT be routinely commissioned.</p> <p>Leeds CCG regards the standing, axially loaded, positional (open) or weight bearing MRI, investigational. There is limited peer-reviewed scientific data available on the accuracy and diagnostic utility of these types of MRIs. Well-designed, larger, clinical trials are necessary to effectively determine the evidence showing the degree to which such methods are safe, effective and more accurate than conventional MRI for use as diagnostic tools.</p> <p>Leeds CCG does not support whole spine or body imaging</p>
<p><u>Commissioned as an exception where all the following criteria are met, note prior approval is always required:</u></p>	<p>Clinically urgent cases (required within 14 days)</p> <p>In most cases where clinically urgent a normal MRI scanner would be preferable and could be arranged with sedation etc as necessary. If an upright MRI scan is requested as an urgent case this will need to have been discussed with a consultant radiologist to exclude other means of accessing imaging.</p> <p>Non clinically urgent cases (not required within 14 days)</p> <p>Referral for open MRI scanning of at least 0.5T as an alternative to conventional MRI may be commissioned in the following circumstances as an exception <u>where all the criteria are met in full:</u></p> <ul style="list-style-type: none"> • patients who suffer from claustrophobia where an oral prescription sedative has been tried and documented in clinical notes that this not been effective (flexibility in the route of sedative administration may be required in paediatric patients as oral prescription may not be appropriate) <p>OR</p> <ul style="list-style-type: none"> • patients who are obese and cannot fit comfortably in conventional MRI scanners as determined by a Consultant Radiologist/Radiology department policy (LTH largest bore is 70 cm and the weight limit 250 kg; The issue re size is how the weight is distributed). <p>OR</p> <ul style="list-style-type: none"> • patients who cannot lie properly in in conventional MRI scanners because of severe pain

	<p>AND The purpose of the scan is a last resort to exclude larger lesions if this is clinically relevant <u>in the brain and spine</u>. Peripheral body parts will not normally be considered for upright MRI unless at the specific request of an acute consultant who believes this is essential to clinical management due to failed trial of single body part MRI.</p> <p>AND A consultant led clinical team (be it MSK service ,orthopaedics or neurosciences) has reviewed the case or directly initiated the request, and make a recommendation following discussion with a consultant radiologist that upright MRI is clinically essential to the management of the case.</p> <p>IN ADDITION The CCGs will only fund uMRI of the specific anatomy requested.</p>
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4.0 Background

Washington State Health Care Authority Health Technology Assessment identifies upright, standing or positional MRI (uMRI) as a type of vertically, open MRI that has been developed in recent years. Such systems are open at the front and top, with the magnetic poles placed on either side of the patient and allow for vertical (upright, weight bearing), horizontal (recumbent) positioning, and dynamic kinetic flexion and extension manoeuvres. Current uMRI scanners generally use medium field magnets of 0.5T or 0.6T). uMRI is any system of 0.5T or greater that allows for scanning in various positions, regardless of manufacturer. By comparison, the most advanced standard rMRI scanners have magnet strength of at least 1.0T and up to 3.0T allowing for the greatest resolution generally in a shorter amount of time. With 0.6T magnets, uMRI requires more time to obtain images with lower resolution. Slower imaging times with uMRI may create difficulty for patients who are unable to remain still while in a standing or sitting position; not comfortable secondary to pain; or are unstable in such positions. Longer exam times may also decrease the overall patient flow and volume of patients that can be accommodated. The proposed advantages of uMRI are based on the ability to scan the spine (or joints) in different positions (including the position where clinical symptoms are more pronounced) and assess the effects of weight bearing, position and dynamic movement. It is hypothesised that uMRI scanning in a variety of positions could help elucidate pathology that may be expressed more fully with positional changes or weight bearing.

MRI has in many instances, become the diagnostic modality of choice for evaluating suspected causes of such pain. It is hypothesized that uMRI, by obtaining images in the axial-loaded condition, and/or while the patient is in a position which elicits symptoms, may facilitate the diagnosis of various abnormalities that cause the symptoms. No formal technology assessments, systematic reviews or critiques of evidence quality related to the diagnostic accuracy or reliability of uMRI used in the evaluation of the spine and extra-spinal joints have been found in the published, peer-reviewed literature.

One study by Hirasawa et al. (2007) recruited 29 healthy male subjects to undergo MR imaging of the spine in the supine, standing, and seated (neutral, flexion, and extension) positions. Changes in the mean cross-sectional areas and diameters comparing these positions were reported. The authors found significantly smaller mean dural sac cross-sectional areas at all spinal levels in the supine position versus the upright positions.

This percent decrease was as large as 25.4% (supine versus seated extension at the L5/S1 level). Measurements of the mean dural sac diameter showed both increases and decreases comparing the different positions. This study utilized a 0.6T open MRI for all images.

Karadimas et al. (2006) studied 30 subjects with chronic degenerative low back pain who were wait-listed for surgery. They evaluated changes in mean end plate angles and disc height for all lumbar intervertebral levels in the supine position versus the seated neutral position. They utilized a 0.2T open MRI for images in the supine position, and a 0.6T upright scanner for images in the seated position. They also assessed lumbar lordosis. The authors classified discs into four degrees of degeneration (healthy, mild, moderate, or severe). For degenerated discs and healthy discs below degenerated discs, there was a significant reduction in mean end plate angles ranging from -1.7° to -6.8° in the seated position relative to the supine position. The authors reported both increases and decreases in disc height for degenerated discs and healthy discs comparing the supine to the sitting position. There was no clear trend in these changes. Finally, no significant change in lumbar lordosis comparing the two positions was found. This study contributes to a greater Upright MRI report understanding of spinal kinematics; however, it does not address whether uMRI improves diagnosis of disc degeneration compared with rMRI.

A study by Kanno et al. (2011) reported the findings of a study of 44 consecutive subjects who underwent imaging with conventional MRI, axial MRI and upright myelogram. The measurements of the transverse and anteroposterior diameters, as well as the cross sectional areas of the dural sac from L2/3 to L5/S1 from all three imaging methods were compared. The authors reported that results from axial loaded MRI demonstrated a significant reduction in the dural sac size and significant correlations of the dural sac diameters with the upright myelogram ($p < 0.001$). Furthermore, the axial loaded MRI had higher sensitivity and specificity than the conventional MRI for detecting the severe constriction observed in the myelogram (96.4% vs. 83.9% and 98.2% vs. 87.0%, respectively). While these findings are promising, further investigation into how axial MRI can improve health outcomes compared to conventional MRI is warranted.

Washington State Health Care Authority found that there was insufficient scientific evidence to make any conclusions about upright MRI's effectiveness, including whether upright MRI: accurately identifies an appropriate diagnosis; can safely and effectively replace other tests; or results in equivalent or better diagnostic or therapeutic outcomes.

A number of studies have reported that positional MRI can identify abnormalities in patients where conventional MRI did not identify significant abnormal findings. As yet, no studies have been noted that describe clinical outcomes of patients whose treatments were selected based on the new findings of positional MRI. Additionally, the incremental benefit of this imaging in clinical practice is not yet known.

The majority of the articles found on 'Stand-Up MRI's' are from the various radiology groups and are in the form of reviews. Additional evidence-based studies are needed to determine the characteristics of patients who might benefit from positional MRI studies. In addition, the clinical benefit of basing treatment decisions, including surgery, on these additional findings need to be established. Another concern that needs further study is that positional scans, which use lower strength magnets, may be of lesser quality than those from traditional supine MRI.

In summary, there continues to be minimal published and peer-reviewed scientific evidence from studies designed to minimize potential biases showing how weight-bearing MRI contributes to the planning and delivery of therapy or to improved health outcomes among patients.

Subacute and chronic low back pain is a significant health problem, affecting approximately 80% of adults at some time in their lives. In many cases, this pain is due to arthritis, abnormal spinal curvature, pinched or compressed nerves, or deterioration of the discs that separate vertebrae. Other less common causes of back pain are cancer, infection, injury, and damage from prior surgery. Although back pain occurs most often in the lower spine, it can also occur in the mid and upper spine.

Imaging techniques that have been used to diagnose spinal disorders include magnetic resonance imaging (MRI), computed tomography (CT), discography, and myelography. The latter two techniques involve taking series of x-rays after injection of a contrast agent into the spinal disc or into the space around the spinal cord. However, all of these techniques except MRI expose patients to radiation and myelography and discography are invasive. The National Institute for Health and Care Excellence (NICE) suggests considering MRI when a diagnosis of spinal malignancy, infection, fracture, cauda equina syndrome or ankylosing spondylitis or other inflammatory disorders are suspected but only to offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion.

4.1 Conventional MRI

Conventional MRI is established as the most sensitive imaging test of choice of the spine in routine clinical practice. MRI imaging of the spine is performed to:

- Assess the spinal anatomy;
- Visualize anatomical variations and diseased tissue in the spine;
- Assist in planning surgeries on the spine such as decompression of a pinched nerve or spinal fusion;
- Monitor changes in the spine after an operation, such as scarring or infection;
- Guide the injection of steroids to relieve spinal pain;
- Assess the disks, (i.e. bulging, degenerated or herniated intervertebral disk, a frequent cause of severe lower back pain and sciatica);
- Evaluate compressed (or pinched) and inflamed nerves;
- Explore possible causes in patients with back pain (compression fracture for example);
- Image spinal infection or tumours that arise in, or have metastasized to, the spine;
- Assess children with daytime wetting and an inability to fully empty the bladder.

The absence of axial loading and lumbar extension results in a maximization of spinal canal dimensions, which may in some cases, result in failure to demonstrate nerve root compression. Attempts have been made to image the lumbar spine in a more physiological state, either by imaging with flexion–extension, in the erect position or by using axial loading.

4.2 Axially Loaded MRI

A modification of conventional MRI, known as axially loaded MRI, has been developed. The axial loading refers to the application of a force on a subject's body to simulate weight-bearing. For this technique, patients put on a special harness that compresses

the spine while they lie in the MRI scanner but this procedure may not accurately reproduce the weight-bearing state.

4.3 Positional MRI

Positional MRI has been developed to provide images of the spine under true weight-bearing conditions. This technique relies on a vertically open configuration MRI scanner in which the circular magnets have been turned on end. The patient sits or stands between the magnets during image collection and can adopt various positions such as flexion or extension of the neck or back, allowing imaging of the spine under conditions that occur in daily life.

Standing or sitting MRIs may be performed with patients in different positions (eg. extension, flexion, neutral) for comparison of anatomy in various positions. It is theorized that such positional imaging may provide information not available from methods currently used (i.e. supine conventional MRI) and that this added information will lead to improved diagnosis, treatment and outcomes.

Madsen et al. (2008) completed two separate studies of patients with lumbar spinal stenosis, including 16 and 20 patients, respectively. In section 1, MRI scans were performed during upright standing and supine positions with and without axial load. In section 2, MRI scans were performed exclusively in supine positions, one with flexion of the lumbar spine (psoas-relaxed position), an extended position (legs straight), and an extended position with applied axial loading. Disc height, lumbar lordosis, and dural sac cross-sectional area (DCSA) were measured and the different positions were compared. In section 1, the only significant difference between positions was a reduced lumbar lordosis during standing when compared with lying ($P = 0.04$), most probably a consequence of precautions taken to secure immobility during the vertical scans. This seemingly makes our standing posture less valuable as a standard of reference. In section 2, DCSA was reduced at all 5 lumbar levels after extension, and further reduced at 2 levels after adding compression ($P < 0.05$). Significant reductions of disc height were found at 3 motion segments and of DCSA at 11 segments after compression, but these changes were never seen in the same motion segment. Horizontal MRI with the patient supine and the legs straightened was comparable to vertical MRI whether axial compression was added or not. Extension was the dominant cause rather than compression in reducing DCSA. Axial load was **not** considered to have a clinically relevant effect on spinal canal diameters.

Karadimas et al. (2006) completed a peer-reviewed study that compared upright MRI with conventional MRI. This study enrolled 30 patients with chronic, degenerative low back pain, who were candidates for surgery due to failure of conservative treatments. The mean patient age was 44.5 years (range 25 to 61) and 16 (53%) of the patients were women. Imaging studies were used to examine 5 intervertebral discs in the lower back and disc disease on a per-disc basis was classified as mild (11%), moderate (23%), or severe (9%). The remaining discs were deemed healthy. After classifying disc degeneration, end-plate angles and disc heights were compared for patients in the supine and sitting positions. For degenerated discs and healthy discs below degenerated discs, there was a statistically significant 1.7° to 6.8° decrease in mean end-plate angle in the sitting position versus the supine position ($P < 0.02$). Likewise, for degenerated discs and healthy discs above degenerated discs, there were statistically significant differences in mean anterior and/or middle disc heights in the sitting versus the supine position ($P < 0.05$). However, in some cases mean disc heights increased and in other cases mean disc heights decreased. No significant changes in lumbar lordosis were observed when patients were in the sitting versus the supine positions.

They do **not** address whether positional MRI improves diagnosis of disc degeneration compared with conventional MRI.

Washington State Department of Labor and Industries: Washington State published a Health Technology Assessment on Standing, Weight-Bearing, Positional, or Upright MRI (2006). They concluded:

- There is limited scientific data available on the accuracy and diagnostic utility of standing, upright, weight-bearing or positional MRI.
- There is no evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations.
- Due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weightbearing, positional MRI is considered investigational and experimental.

Jinkins et al. (2005) stated that weight-bearing open-design MRI allows for improved sensitivity and specificity; however, no supporting data was provided. Vitaz et al. (2004) used a 0.5 T MRI scanner to prospectively evaluate the first 20 patients referred for MRI for neck pain. There was no comparator; no comparison to conventional MRI can be drawn.

Weishaupt et al. (2003) stated that conventional MRI of the lumbar spine (i.e., in the supine position) remains the imaging method of choice for the assessment of degenerative disk disease.

A Medline search identified five studies that evaluated upright MRI for spinal disorders; three that compared upright MRI with conventional MRI and one that compared upright MRI with myelography. Results of these studies suggest that upright MRI provides diagnostic information similar to that provided by conventional imaging techniques; however, these studies do **not** provide convincing evidence that upright MRI improves diagnosis of spinal disorders. Although some altered spinal features were seen with upright MRI that were not seen with conventional MRI, the incidence of these altered features was either not statistically significant, the statistical significance was not reported, or it was not clear whether the altered features could be relied on to provide a more accurate diagnosis. For example, one small study found that upright MRI revealed statistically significant changes in the positions of vertebrae next to degenerated spinal discs but these discs had already been diagnosed as degenerate based on images from conventional MRI. In comparison with myelography, a small study found that this technique and upright MRI provided comparable data concerning the mean diameters of dural sacs, the membranous sacs that surround the spinal cord. A serious shortcoming of the studies that compared upright MRI with conventional MRI is that none of them involved axially loaded conventional MRI to determine whether this modification would reveal spinal alterations similar to those observed during upright MRI. Moreover, all of the available studies were relatively small and none of these studies investigated whether information provided by upright MRI improved the management of patients or their final outcomes. Well-designed studies with larger study populations are needed to determine whether upright MRI provides benefits compared with current standard imaging techniques.

There is only minimal evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations. Though positional, weight-bearing MRI is cited as allowing for improvement in sensitivity and specificity, no studies appear to have addressed the diagnostic accuracy compared to conventional MRI or other diagnostic tests. There is minimal

published and peer-reviewed scientific evidence from studies designed to minimize potential biases showing how weight-bearing MRI contributes to the planning and delivery of therapy (therapeutic impact) or to improved health outcomes (impact on health) among patients generally or among injured workers. Due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weight-bearing, and positional magnetic resonance imaging are considered investigational.

4.4 Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be at the relevant Leeds Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

5.0 References

This policy is based on the following evidence-based guidelines:

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Appendix A: Version Control Sheet

Version	Date	Author	Status	Comment
Draft 1	1.8.13	Jon Fear	Draft	Draft policy
Draft 2	9.9.13	Fiona Day	Draft	Draft with cover sheet
Draft 3	18.11.13	Fiona Day	Draft	Amendment of review date; addition of endpoints.
Draft 4	29.11.13	Fiona Day	draft	Addition of Providers will not be paid for any activity with regards this framework which has not been approved in advance. Addition of dissemination plan
Final amended	28.5.15	Fiona Day	amended	Amended following discussion with Consultant Radiologist.
Updated	April 2018		Amended	Amended following merger of the 3 CCGs in Leeds – no change to clinical content following further consultant with Lead Clinician

Appendix B: - Equality Impact Assessment

Title of policy	Use of an upright, standing or positional (open) MRI scanner	
Names and roles of people completing the assessment	Fiona Day, Consultant in Public Health Medicine, Leeds City Council	
Date assessment started/completed	April 2018	April 2018

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the Leeds CCG to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCG. This policy relates to requests for Ear Nose and Throat procedures.
What outcomes do you want to achieve	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Analysis of impact			
This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to; eliminate unlawful discrimination; advance equality of opportunity; foster good relations			
	Are there any likely impacts? Are any groups going to be affected differently? Please describe.	Are these negative or positive?	What action will be taken to address any negative impacts or enhance positive ones?
Age	No		
Carers	No		
Disability	No		
Sex	No		

Race	No		
Religion or belief	No		
Sexual orientation	No		
Gender reassignment	No		
Pregnancy and maternity	No		
Marriage and civil partnership	No		
Other relevant group	No		
4. Monitoring, Review and Publication			
If any negative/positive impacts were identified are they valid, legal and/or justifiable? Please detail.			

4. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	n/a		
Lead Officer	Dr Simon Stockill	Review date:	9 May 2018

5. Sign off			
Lead Officer	Dr Simon Stockill, Medical Director		
Director		Date approved:	9 May 2018