Commissioning Policy
for use of an upright, standing or positional (open) MRI scanner

Version: 6
Committee Approved by: NHS Wakefield CCG Clinical Cabinet
Date Approved: February 2016
Author: Commissioning Manager (Service Improvement and Transformation)
Responsible Directorate: Commissioning
Date issued: March 2016
Review date: June 2017
## Version Control Sheet

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<th>Status</th>
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<td>March 2016</td>
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<td>Approved by Clinical Cabinet February 2016. GPs in Wakefield District can refer directly to Upright MRI using the referral criteria.</td>
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1 Introduction

This policy is designed to clarify the agreements between NHS Wakefield CCG and providers for 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.

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

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

1.1 Scope of the Policy

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

The policy identifies clear criteria to enable decisions to be made by local referrers, or to support decisions of the Individual Funding Request Panel where further consideration is required and requests do not meet the policy criteria.

1.2 Definitions

**Commissioner** – NHS Wakefield Clinical Commissioning Group (CCG)

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

**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.

**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. Positional MRI has been developed to provide images of the spine under true weight-bearing conditions. 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.

2 Rational for Policy

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. 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.

Please see Appendix 1 for evidence-based review.

3 Criteria for Funding

<table>
<thead>
<tr>
<th>Not routinely commissioned</th>
<th>Standing, upright, weight-bearing or positional (open) MRI will not be routinely commissioned.</th>
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<tr>
<td></td>
<td>Wakefield CCG regard the standing, axially loaded, positional (open) or weight bearing MRI, investigational.</td>
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<td></td>
<td>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.</td>
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<td><strong>Commissioned as an exception where all the following criteria are met, note prior approval is always required:</strong></td>
<td><strong>Clinically urgent cases (required within 14 days)</strong></td>
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<td>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.</td>
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<td><strong>Non clinically urgent cases (not required within 14 days)</strong></td>
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<td>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 where all the criteria are met in full:</td>
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<td>• patients who suffer from claustrophobia where an oral prescription sedative has not been effective (flexibility in the route of sedative administration may be required in paediatric patients as oral prescription may not be appropriate)</td>
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<td>or</td>
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<td></td>
<td>• patients who are obese and cannot fit comfortably in conventional MRI scanners as determined by a Consultant Radiologist/Radiology department policy. The issue re size is how the weight is distributed.</td>
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<td>or</td>
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<td></td>
<td>• patients who cannot lie properly in conventional MRI scanners because of severe pain</td>
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<td><strong>AND</strong></td>
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<td>The purpose of the scan is a last resort to exclude larger lesions if this is clinically relevant in the brain and spine. 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.</td>
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<td></td>
<td><strong>AND</strong></td>
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<td>The patient is registered with a Wakefield GP Practice</td>
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<td><strong>IN ADDITION</strong> The CCGs will only fund uMRI of the specific anatomy requested.</td>
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4 **Evidence**

Please see Appendix 1 for full review of evidence-based guidelines.

5. **Accountability**

Commissioning Support Officers can use the policy under the direction of Senior Commissioning Managers and the Head of Quality. Ultimate accountability for the policy is with the Director of Quality & Commissioning.
6 Equality Impact Assessment

NHS Wakefield CCG aims to design and implement services, policies and measures that meet the diverse needs of our service users, population and workforce, ensuring that none are placed at a disadvantage over others. An Equality Impact Assessment has been carried out (see Appendix 2) and as a result, a review will be carried out annually to determine whether there is any new evidence available which would extend the scope of the policy to a wider range of disabilities.

7 Monitoring Compliance with and the Effectiveness of Procedural Documents

This Policy will form an appendix to NHS Wakefield CCG General Commissioning Policy, and will be reviewed on an annual basis.

The Senior Commissioning Manager will ensure the policy is assessed and monitored appropriately.

NHS Wakefield CCG will ensure that this policy is reviewed in light of new national guidance and routinely reviewed on an annual basis.

8 Associated Documentation

NHS Wakefield CCG, General Commissioning Policy

9 References

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

18. Hailey D. Open magnetic resonance imaging (MRI) scanners. Issues in Emerging Health Technologies. Issue 92. Ottawa, Canada; Canadian Agency for Drugs and Technologies in Health (CADTH); 2006.
29. Smith FW, Wardlaw D. Dynamic MRI Using the Upright or Positional MRI Scanner, in Spondylolysis, Spondylolisthesis, and Degenerative
Appendix 1
Evidence-based Review

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.

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.

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.
### Appendix 2

**Equality Impact Assessment**

**Screening Process Template – Equality Impact Assessment**

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<thead>
<tr>
<th>1. Name of policy, strategy, project or service:</th>
<th>Upright, standing or positional MRI scanner policy</th>
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| 2. What are the main aims and objectives of the policy / strategy or project? | - To establish guidelines under which it is appropriate to fund the use of an open MRI scanner.  
- To ensure that funding is based on evidence that the patient is likely to benefit from the use of equipment. |
| 3. Could any groups be negatively affected by this policy/ strategy? | Yes | No |
| Referrals will be assessed solely against the stated criteria which is based on ability to benefit, therefore all assessment will be equitable. Evidence will be reviewed annually to determine whether the policy should extend the scope either in terms of disability range. |
| 4. Could there be a negative impact under current legislation? | Yes | No |
| Please explain: Referrals will be assessed solely against the stated criteria which is based on ability to benefit, therefore all assessment will be equitable. |
| 5. Based on the screening process please indicate if this policy should proceed to a full impact assessment or monitoring? | Full impact assessment | Monitoring |
| Please explain: The evidence will be reviewed annually to ensure that this diagnosis is available to those groups where there is good evidence of benefits. |

Name (Lead Officer) ___ Sarah Shepherd ________ Date __ 16th September 2015 __

Signed (Lead Officer) _________________________________