

**Greater Manchester Shared Services** 

# Greater Manchester EUR Policy Statement on:

# Wide bore, open and open upright MRI scanning GM Ref: GM045

Version: 1.0 (9 Jan 2018)



**Greater Manchester Shared Services** Hosted by NHS Oldham CCG on behalf of the Greater Manchester CCGs

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## **Commissioning Statement**

	Wide bore, open and open upright MRI scanning		
Policy Exclusions	Standard MRI scans indicated as part of a care pathway are considered routine and are excluded from this policy.		
	Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).		
Policy Inclusion Criteria	As the demand for MRI imaging increases so does the demand for different types of scanner. The main reasons for alternative scanners being requested are claustrophobia and obesity, with a few being requested for clinical reasons (usually upright scans).		
	This policy aims to manage access to alternative scanners in an equitable way based on need whilst managing a scarce resource.		
	The majority of patients should be referred for a standard MRI scan in the normal way however, if they are unable to undergo scanning in this way due to claustrophobia or obesity, then they should be managed as follows below.		
	The referrer needs to be aware of the limitations (e.g. resolution of the resulting image impacting on the quality of the scan result) for each type of scanner being considered before referring for a non-standard scan.		
	Claustrophobia <sup>2</sup> (open scanning)		
	• Standard scanning should be tried under oral sedation in the first instance unless this is clinically contraindicated.		
	• IV sedation can be tried if suitably qualified staff are available to administer it.		
	<ul> <li>Scanning using general anaesthesia should only be undertaken where:         <ul> <li>the patient has an underlying condition e.g. a movement disorder - that prevents them from remaining still in the scanner (whatever the type being used)</li> </ul> </li> <li>OR</li> </ul>		
	<ul> <li>It is considered essential for the clinical management of the patient and no alternative is available.</li> <li>AND</li> </ul>		
	<ul> <li>All other options to attain a scan have been tried and failed.</li> </ul>		
	NOTE:		
	• The provision and administration of sedation is the responsibility of the provider and where intravenous or general anaesthesia is used full back up to deal with any complications from the anaesthesia must be available on site.		
	• If the claustrophobia persists despite sedation, or sedation cannot be given, then the patient can be referred for an open scan within an NHS provider (or any other provider commissioned to provide this type of service to the NHS).		
	• Applications for wide bore or open scan referrals <u>must</u> include the following information:		
	<ul> <li>A clinical letter confirming the diagnosis of claustrophobia</li> </ul>		

	$\circ$ Any information relating to previous, failed, attempts at a scan	
	Funding Mechanism	
	Individual prior approval provided the patient meets the above criteria. Requests <u>must</u> be submitted with all relevant supporting evidence.	
	Obesity <sup>6.7</sup> (wide bore scanning)	
	• If the patient cannot fit into a standard scanner then refer to an NHS provider (or any other provider commissioned to provide this type of service to the NHS) with a wide bore scanner. <b>NOTE:</b> These can manage patients up to 550lbs in weight (patients with a lower weight but an increased girth may not be suitable – please be aware of the girth limitation prior to referral).	
	• If the patient is unsuitable for a wide bore scanner they should be referred for an open scan at an NHS provider (or any other provider commissioned to provide this type of service to the NHS).	
	With high-field, wide-bore MRIs, the extra-wide bore architecture makes it comfortable for patients of all sizes (up to 550lbs/ 39st 4lbs / approx. 249.47kg). The diameter of the bore is 27.5 inches / approx. 69.85cm versus 23.5 inches / approx. 59.69cm; allowing typical patients 1 foot of headroom and more elbowroom.	
	<u>NOTE:</u> Applications for wide bore or open scan referrals <u>must</u> include an up to date BMI and girth measurement.	
	Funding Mechanism	
	Individual prior approval provided the patient meets the above criteria. Requests <u>must</u> be submitted with all relevant supporting evidence.	
	Clinically indicated upright scanning	
	• If an upright scan is required for clinical reasons then patients may be referred to an NHS provider (or any other provider commissioned to provide this type of service to the NHS) with an open upright scanner.	
	• If a patient is unable to lie flat for the duration of the scan for medical reasons, including extreme pain, they may be referred for an open upright scan at an NHS provider (or any other provider commissioned to provide this type of service to the NHS).	
	<u>NOTE:</u> Applications for wide bore or open scan referrals <u>must</u> include a clinician letter stating the clinical indications in this case necessitating an upright scan.	
	Funding Mechanism	
	Individual funding request (exceptional case) approval: Requests <u>must</u> be submitted with all relevant supporting evidence. <u>NOTE:</u> Requests for an upright scan for the above reasons should come from the specialist managing the condition under investigation.	
Clinical Exceptionality	Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.	
	Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality;	

however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:
• Significantly different to the general population of patients with the condition in question.
and as a result of that difference
• They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

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#### **Policy Statement**

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

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

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

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

#### Equality & Equity Statement

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

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

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in 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 <u>policyfeedback.gmscu@nhs.net</u>.

#### **Governance Arrangements**

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

#### Aims and Objectives

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

• reducing the variation in access to treatments/procedures.

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

#### Treatment / Procedure

#### Different types of scanner

MRI is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.

#### Standard bore MRI scanner

An MRI scanner is a large tube that contains powerful magnets. The patient lies inside the tube during the scan which can take around 60 mins. The powerful magnets create a great deal of noise during the procedure. An MRI scan can be used to examine almost any part of the body.



Figure 1: Standard bore MRI scanner (Source = NHS Choices)

#### Wide bore MRI scanner

With high-field, wide-bore MRIs, the extra-wide bore architecture makes it comfortable for patients of all sizes (up to 550 lbs). The diameter of the bore is 27.5 inches versus 23.5 inches (traditional MRI scanners), allowing typical patients 1 foot of headroom and more elbowroom. The bore depth is only 3 feet, where traditional short MRI scanners are 4 feet.



Figure 2: Wide bore MRI scanner (Source = Toshiba American Medical Systems)

#### **Open MRI scanner**

The basic technology of an open MRI scanner is similar to that of a conventional MRI scanner. The major difference for the patient is that instead of having to go into a cylinder, our open scanner is open on three sides allowing more space around the body, alleviating feelings of anxiety.



Figure 3: Open MRI scanner (Source = Newcastle Clinic)

#### Upright open MRI scanner

Upright open MRI scanners are able to perform musculoskeletal and neurological dynamic imaging, and weight-bearing imaging. The system is totally open to the environment allowing the patient to be relaxed, cooperative and reassured. It can:

- Scan patients in flexion, extension, rotation and lateral bending
- Scan patients in a sitting position
- Scan patients lying down
- Scan patients in their position of pain
- Scan cardiovascular patients upright to prevent discomfort lying down

The open design of the scanner makes it ideal for scanning claustrophobic patients.



Figure 4: Upright open MRI scanner (Source = the Leeds Upright MRI Centre)

#### Rationale behind the policy statement

Increasing demand for MRI scanning as a key part of care pathways resulting in higher numbers of patients experiencing claustrophobia during a scan. The increase in rates of obesity in the population, particularly morbid obesity, and the increasing availability of different types of scanner has led to an increase in requests for open and upright scans.

This policy aims to target the use of this newer technology to those patients who will get the most benefit.

#### **Epidemiology and Need**

#### Demand for MRI scans<sup>8</sup>

The latest available report on diagnostic imaging covers the year 2013/14. It reported a national figure of 2.4 million magnetic resonance imaging (MRI) events. It noted that in the last 10 years the overall number of tests increased by 39% (an average growth of 3.3% per year), but the volume of MRI scans had increased by 211%.

#### Obesity<sup>7</sup>

In 2014, 58% of women and 65% of men were overweight or obese. Obesity prevalence has increased from 15% in 1993 to 26% in 2014.

The prevalence of morbid obesity (the most severe category of obesity) has more than tripled since 1993, and reached 2% of men and 4% of women in 2014.

#### Claustrophobia in MRI scanners<sup>2</sup>

A recent study found that of the patients examined on a conventional MR scanner 911 of the 42,998 (2.1%) experienced claustrophobia (95% CI, 2.0–2.3%;  $P_{-}$  0.001).

They also found that the rate of claustrophobic reactions was significantly lower amongst patients scanned in a scanner which incorporated noise reduction technology (93 of 12,736 patients (0.7%) 95% CI, 0.6–0.9%).

**NOTE:** Due to the number of conditions that can require an MRI scan, no disease specific epidemiology related to these conditions has been included here.

#### Adherence to NICE Guidance

There is no relevant NICE guidance.

#### Audit Requirements

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

#### Date of Review

One year from the date of approval by Greater Manchester Association Governing Group and thereafter at a date agreed by the Greater Manchester EUR Steering Group, unless new evidence or technology is available sooner.

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

#### Glossary

Term	Meaning
Claustrophobia	Extreme or irrational fear of confined places.
Dynamic imaging	The imaging of an object in motion at a frame rate that does not cause significant blurring of images and at a repetition rate sufficient to represent the movement pattern adequately. Also called real-time imaging.
Extension	An unbending movement around a joint in a limb (as the knee or elbow) that increases the angle between the bones of the limb at the joint.
Flexion	A bending movement around a joint in a limb (as the knee or elbow) that decreases the angle between the bones of the limb at the joint.
Lateral	The side of the body or a body part that is farther from the middle or center of the body.
Lumbar spine	The part of the spine in the lower back.
Magnetic field	A region around a magnetic material or a moving electric charge within which the force of magnetism acts.
Magnetic resonance imaging (MRI)	A technique for producing images of bodily organs by measuring the response of the atomic nuclei of body tissues to high-frequency radio waves when placed in a strong magnetic field.
Radio wave	An electromagnetic wave of a frequency between about 10 <sup>4</sup> and 10 <sup>11</sup> or 10 <sup>12</sup> Hz, as used for long-distance communication.
Rotation	The action or process of rotating on, or as if on, an axis or center; specifically: the turning of a body part about its long axis as if on a pivot.

#### References

- 1. Greater Manchester Effective Use of Resources Operational Policy
- Claustrophobia During Magnetic Resonance Imaging: Cohort Study in Over 55,000 Patients, Marc Dewey, MD, Tania Schink, PhD, and Charles F. Dewey, MD, PhD, Journal Of Magnetic Resonance Imaging 26:1322–1327 (2007)
- 3. North American Spine Society: Evidence based clinical guidelines for multidisciplinary spinal care 2011
- 4. ACR practice parameter for performing and interpreting magnetic resonance imaging (MRI), Amended 2014
- 5. ACR–ASNR–SCBT-MR Practice guideline for the performance of magnetic resonance imaging (MRI) of the adult spine, Revised 2012
- 6. HSCIC Statistics on Obesity, Physical Activity and Diet. England 28 April 2016
- 7. Adult obesity, Health Survey for England (HSE) 2014
- 8. NHS Imaging and Radiodiagnostic activity 2013/14 (NHS England and National Statistics)

## **Governance Approvals**

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	19/07/2017
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	12/12/2017
Greater Manchester Association Governing Group	09/01/2018
Bury Clinical Commissioning Group	09/01/2018
Bolton Clinical Commissioning Group	23/02/2018
Heywood, Middleton & Rochdale Clinical Commissioning Group	09/01/2018
Manchester Clinical Commissioning Group	14/03/2018
Oldham Clinical Commissioning Group	09/01/2018
Salford Clinical Commissioning Group	09/01/2018
Stockport Clinical Commissioning Group	09/01/2018
Tameside & Glossop Clinical Commissioning Group	09/01/2018
Trafford Clinical Commissioning Group	20/02/2018
Wigan Borough Clinical Commissioning Group	28/03/2018

#### Appendix 1 – Evidence Review

# Wide bore, open and open upright MRI scanning GM045

#### Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; BMJ Clinical Evidence; and the relevant royal college websites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken.

No significant evidence of effectiveness between types of MRI scanner was found. There are some technological comparisons available looking at the strength of various scanners and the quality of the image.

#### Summary of the evidence

As this is a diagnostic tool and not a treatment intervention there is no real evidence of effectiveness in relation to types of scanner to be used. There are some American guidelines that include some guidance on the use of upright MRI scans – no similar guidelines were found on the Royal College of Radiologists UK website. There are government guidelines relating to the safe use of MRI scans.

<u>References</u> can be used to see the background information accessed in putting this policy together.

## Appendix 2 – Diagnostic and Procedure Codes

# Wide bore, open and open upright MRI scanning GM045

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

GM045 – Wide bore, open and open upright MRI scanning Note: No codes available specific to open, wide bore or open upright MR	ls
OPCS-4 Procedure Codes:	
Magnetic resonance imaging of whole body	U012
Magnetic resonance imaging of head	U052
Magnetic resonance imaging of spine	U055
Magnetic resonance imaging of chest	U072
Magnetic resonance imaging of abdomen	U085
Magnetic resonance imaging of pelvis	U093
Cardiac magnetic resonance imaging	U103
Magnetic resonance angiography	U117
Magnetic resonance imaging of bone	U133
Magnetic resonance cholangiopancreatography	U162
Magnetic resonance imaging NEC	U211
Magnetic resonance imaging of kidneys	U371
With the following ICD-10 diagnosis codes:	
Specific (isolated) phobias	F402
Obesity due to excess calories	E660
Drug-induced obesity	E661
Extreme obesity with alveolar hypoventilation	E662
Other obesity	E669
Obesity, unspecified	E669

## Appendix 3 – Version History

# Wide bore, open and open upright MRI scanning GM045

The latest version of this policy can be found here: <u>GM MRI scanning (Wide bore, open and open upright) policy</u>

Version	Date	Summary of Changes
0.1	25/02/2017	Initial draft
0.2	15/03/2017	<ul> <li>The GM EUR Steering Group meeting on 15 March 2017, agreed the following changes to the policy:</li> <li><u>Claustrophobia:</u> <ul> <li>'Claustrophobia'</li> <li>Funding mechanism of individual prior approval added</li> </ul> </li> <li><u>Obesity:</u> <ul> <li>'Obesity'</li> <li>Paragraph added after the bullet points: 'With high-field, wide-bore MRIs, the extra-wide bore architecture makes it comfortable for patients of all sizes (up to 550lbs/ 39st 4lbs / approx. 249.47kg). The diameter of the bore is 27.5 inches / approx. 69.85cm versus 23.5 inches / approx. 59.69cm; allowing typical patients 1 foot of headroom and more elbowroom.'</li> <li>Funding mechanism of individual prior approval added</li> </ul> </li> <li>Upright scanning' heading amended to: 'Clinically Indicated Upright scanning'</li> <li>Under the first bullet point, the word 'medical' changed to 'clinical'</li> <li>Funding mechanism of IFR (exceptional case) approval added plus the wording: 'Requests for an upright scan for the above reasons should come from the specialist managing the condition under investigation.'</li> </ul>
0.3	19/07/2017	<ul> <li>The GM EUR Steering Group meeting on 19 July 2017 agreed the following changes to the policy following review of feedback from clinical engagement:</li> <li>Policy Inclusion Criteria <ul> <li>References to 'NHS Provider' have been changed to 'NHS Provider (or any other provider commissioned to provide this type of service to the NHS)'.</li> <li>The following added after the 3rd paragrah: 'The referrer needs to be aware of the limitations (e.g. resolution of the resulting image impacting on the quality of the scan result) for each type of scanner being considered before referring for a non-standard scan.'</li> <li>Claustrophobia (open scanning): Section rewritten to include more details around sedation and note about what referrals should include.</li> <li>Obesity (wide bore scanning): Section rewritten to include note about girth limitation and what referrals should include.</li> <li>Clinically indicated upright scanning: Note about what referrals need to include added.</li> </ul> </li> <li>Treatment / Provider: Under subheading 'Upright open MRI scanner', 'lumbar spine' changed to 'musculoskeletal and neurological'.</li> <li>Glossary: The word 'ultrasonographic' removed from definition of 'Dynamic Imaging' and the first sentence for definition of 'Extension' removed.</li> </ul>

	Following the above changes the GM EUR Steering ( policy could progress through the governance process.	Following the above changes the GM EUR Steering Group agreed that the policy could progress through the governance process.
1.0	09/01/2018	Approved by Greater Manchester Association Governing Group