Greater Manchester EUR Policy Statement on:

Pelvic vein embolisation in the management of varicose veins

GM Ref: GM022

Version: 2.3 (6 June 2018)

Commissioning Statement

Pelvic vein embolisation in the management of varicose veins	
Policy Exclusions **(Alternative commissioning arrangements apply)**	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).
Fitness for Surgery	**NOTE:** All patients should be assessed as fit for surgery before going ahead with treatment, even though funding has been approved.
Policy Inclusion Criteria	As this procedure is still considered experimental it should only be undertaken as part of a clinical trial. It is therefore not routinely commissioned across Greater Manchester. Any trial should have additional costs and exit strategy agreed with the relevant commissioner prior to commencing patients on that trial. **Funding Mechanism** Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.
Clinical Exceptionality	Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality. Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is: • Significantly different to the general population of patients with the condition in question. ***and as a result of that difference*** • They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

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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 policyfeedback.gmscu@nhs.net.

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 GM EUR Operational Policy.

Aims and Objectives

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

- reducing the variation in access to treatments/procedures.

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

Rationale behind the policy statement

At the time of writing this policy there was very little evidence to be found on the role of pelvic vein embolisation in the treatment of varicose veins other than small case studies. Although the limited evidence available did show a positive result, it was small scale and low level. It was noted that a large randomised control trial is planned but at the time of writing the policy it was at the pre-recruitment phase. On the evidence available it was felt that this treatment was developmental and should only be carried out as part of a clinical trial.

Treatment / Procedure

Surgical treatment to cause artificial thrombosis of the pelvic vein.

Epidemiology and Need

There is, at present, no information available on the epidemiology of pelvic vein dilation in relation to symptomatic pelvic congestion and varicose veins. There is some epidemiology available on the general prevalence of pelvic congestion but is too non-specific to be helpful in this context.

Adherence to NICE Guidance

NICE have not currently issued guidance on this treatment.

Audit Requirements

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

Date of Review

The date of the future review of the policy has been adjusted in line with the clinical trial NCT01909024 end date to be carried out around the end of 2018, unless NICE or other similar guidance is issued that would require the review to be brought forward.

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
Congestion	The state of being overloaded or clogged with blood.
Embolisation	Surgical procedure intended to occlude a blood vessel to stop haemorrhaging or to block off the blood supply.

Pelvic	Relating to or situated within the bony pelvis.

References

1. GM EUR Operational Policy
2. York Review: Percutaneous transcatheter coil embolization for Pelvic Congestion Syndrome (PCS), Published: June 2012
3. Pelvic vein embolisation in the management of varicose veins, Ratnam LA et al, Cardiovasc Intervent Radiol. 2008 Nov-Dec;31(6):1159-64. doi: 10.1007/s00270-008-9402-9. Epub 2008 Aug 28.
4. Pelvic vein incompetence: a review of diagnosis and treatment, Giuseppe ASCIUTTO (Malmö, Sweden), Phlebolymphology Vol 19 No 2 2012 • p57-104

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	09/07/2014
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	12/08/2014
Greater Manchester Association Governing Group	Sep 2014
Bury Clinical Commissioning Group	05/11/2014
Bolton Clinical Commissioning Group	24/10/2014
Heywood, Middleton & Rochdale Clinical Commissioning Group	19/09/2014
Manchester Clinical Commissioning Group	North: 12/11/2014 Central: 23/10/2014 South: 21/01/2014
Oldham Clinical Commissioning Group	02/10/2014
Salford Clinical Commissioning Group	01/10/2014
Stockport Clinical Commissioning Group	22/10/2014
Tameside & Glossop Clinical Commissioning Group	15/10/2014
Trafford Clinical Commissioning Group	16/09/2014
Wigan Borough Clinical Commissioning Group	05/11/2014

Appendix 1 – Evidence Review

Pelvic vein embolisation in the management of varicose veins
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Search Strategy

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

Database	Result
NICE	Nil in guidelines
NHS Evidence	Clinical trial NCT01909024: Pelvic Embolisation to Reduce Recurrent Varicose Veins – Recurrent (not yet recruiting)
	York Review (see below)
York	York Review: Percutaneous transcatheter coil embolization for Pelvic Congestion Syndrome (PCS), Published: June 2012
General Search (Google)	Pelvic vein embolisation in the management of varicose veins, Ratnam LA et al
	Pelvic vein incompetence: a review of diagnosis and treatment, Giuseppe ASCIUTTO (Malmö, Sweden)

Summary of the evidence

There was very little evidence to be found on the role of pelvic vein embolisation in the treatment of varicose veins other than small case studies. A large randomised control trial is planned but is at the pre-recruitment phase. This treatment is experimental at present.

Level of evidence N/A at present will be level 2 when reported.

September 2015: No additional evidence, over and above that contained in the current policy, was found. The proposed trial identified in the original search (Clinical trial NCT01909024 Pelvic Embolisation to Reduce Recurrent Varicose Veins) is now in the recruitment phase – the recruitment start date was July 2013 and the proposed end date is October 2018.

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series

Level 5	Expert opinion

1. LEVEL N/A: PROTOCOL

Clinical trial NCT01909024: Randomised Controlled Trial Investigating The Use Of Pelvic Vein Embolisation to Reduce Recurrent Varicose Veins Of The Legs In Women With Recurrent Varicose Veins And Associated Pelvic Venous Reflux (not yet recruiting)

Condition to be studied is Varicose Veins.

Venous Reflux with Pelvic Congestion Syndrome treated by Coil embolization. The aim of this study is to identify whether the treatment of pelvic venous reflux (pelvic embolisation) in females with recurrent leg varicose veins, who have a proven contribution to their leg varicose veins from pelvic venous reflux, have a reduction in future recurrence after endovenous laser treatment for recurrent varicose veins in the legs.

2. LEVEL 5: CLINICAL REVIEW

York Review: Percutaneous transcatheter coil embolization for Pelvic Congestion Syndrome (PCS), Published: June 2012

Chronic pelvic pain is reported by up to one-third of women at some point in their lives and accounts for around 15% of outpatient gynecological visits. In approximately 30% of patients with chronic pelvic pain, the pain is associated with distended or varicose veins in the pelvis (specifically the ovarian and internal iliac veins), referred to as pelvic congestion syndrome. It is believed that swollen pelvic veins cause nerve irritation and the dull pain, which may be worse after prolonged standing or intercourse. Although the exact cause is unknown, weight gain, fluid retention, and hormonal changes during pregnancy might play a role. Diagnosis is difficult due to the number of conditions that cause similar symptoms, and definitive diagnosis may require ultrasound, computed tomography, and/or magnetic resonance imaging, and venography (x-rays following the injection of a dye into the affected veins). There is no consensus on the best treatment for pelvic congestion syndrome. Standard therapies include pain medications, hormonal therapy, and surgery including vein ligation or hysterectomy. The report may be purchased from: http://www.hayesinc.com/hayes/crd/?crd=12958

3. LEVEL 4: CASE SERIES

Pelvic vein embolisation in the management of varicose veins, Ratnam LA et al, Cardiovasc Intervent Radiol. 2008 Nov-Dec;31(6):1159-64. doi: 10.1007/s00270-008-9402-9. Epub 2008 Aug 28.

Abstract

Pelvic vein incompetence is common in patients with atypical varicose veins, contributing to their recurrence after surgery. Therefore, refluxing pelvic veins should be identified and treated. We present our experience with pelvic vein embolisation in patients presenting with varicose veins. Patients presenting with varicose veins with a duplex-proven contribution from perivulval veins undergo transvaginal duplex sonography (TVUS) to identify refluxing pelvic veins. Those with positive scans undergo embolisation before surgical treatment of their lower limb varicose veins. A total of 218 women (mean age of 46.3 years) were treated. Parity was documented in the first 60 patients, of whom 47 (78.3%) were multiparous, 11 (18.3%) had had one previous pregnancy, and 2 (3.3%) were nulliparous. The left ovarian vein was embolised in 78%, the right internal iliac in 64.7%, the left internal iliac in 56.4%, and the right ovarian vein in 42.2% of patients. At follow-up TVUS, mild reflux only was seen in 16, marked persistent reflux in 6, and new reflux in 3 patients. These 9 women underwent successful repeat embolisation. Two patients experienced pulmonary embolisation of the coils, of whom 1 was asymptomatic and 1 was successfully retrieved; 1 patient had a misplaced coil protruding into the common femoral vein; and 1 patient had perineal thrombophlebitis. The results of our study showed that pelvic venous embolisation by way of a transjugular approach is a safe and effective technique in the treatment of pelvic vein reflux.

4. LEVEL 5: REVIEW

Pelvic vein incompetence: a review of diagnosis and treatment, Giuseppe ASCIUTTO (Malmö, Sweden), Phlebolymphology Vol 19 No 2 2012 • p57-104

Abstract

Pelvic vein incompetence is often associated with typical clinical signs of congestion as well as pelvic pain. This clinical entity is often underestimated and patients suffering from pain related to pelvic varicosities undergo a long and inconclusive diagnostic workup before the exact cause of symptoms is recognized. Besides the typical chronic pelvic pain, signs such as vulvar varicosities are not always present. Because of the wide variation of clinical and radiological presentations, there is a general consensus that diagnostic and therapeutic approaches should be patient-tailored. To date, non-invasive diagnostic techniques including ultrasound, computed tomography, and magnetic resonance imaging have been used to identify patients who are candidates for treatment. Venous embolization is now accepted worldwide as the treatment of choice, because of its promising results in terms of clinical success and its limited invasiveness. This article reviews currently available diagnostic and therapeutic options.

Appendix 2 – Diagnostic and Procedure Codes

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

GM022 - Pelvic Vein Embolisation Policy	
Percutaneous transluminal embolisation of vein; plus	L94.1
Ovarian vein	Z93.2
With the following ICD-10 diagnosis code(s):	
Pelvic varices	I86.2
Pelvic and perineal pain	R10.2

Appendix 3 – Version History

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The latest version of this policy can be found here: GM Pelvic Vein Embolisation in the management of varicose veins policy

Version	Date	Summary of Changes
0.1	12/11/2013	Initial draft
0.2	10/12/2013	• Paragraph under 5. 'Description of Epidemiology and Need' amended to explain the lack of epidemiological evidence, as per agreed action at GM EUR Steering Group on 20/11/13. • Draft Policy approved by GM EUR Steering Group on 15/01/2014.
0.3	19/02/2014	Rationale behind policy statement included.
0.4	08/04/2014 17/04/2014 09/07/2014	• Statement regarding treating disabled people as more equal than other protected characteristic groups added to Equality and Equity section. • Ratification through CCG Governing Bodies added to 'Governance Arrangements'. Policy published for consultation. Policy reviewed by GM EUR Steering Group following consultation.
1.0	09/07/2014	Policy approved by Greater Manchester EUR Steering Group
2.0	Sept 2015 18/11/2015	Policy reviewed - No additional evidence, over and above that considered in the current policy was found (Evidence Review Section update to reflect this). • The GM EUR Steering Group therefore agreed that the commissioning stance in the current policy remains unchanged but added under Policy Exclusions that treatment as part of a locally agreed pathway of care or pre-agreed and funded trial are excluded from this policy. • The date of the future review of the policy has been adjusted in line with the clinical trial NCT01909024 end date to be carried out around the end of 2018, unless NICE or other similar guidance is issued that would require the review to be brought forward.
2.1	05/04/2016	• List of diagnostic and procedure codes in relation to this policy added as Appendix 3. • Policy changed to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.
2.2	14/12/2016	Appendix 3: Removed Procedure Code Z93.9 Vein of pelvis NEC
2.3	06/06/2018	• Policy moved to new format and some wording rearranged and clarified • Appendix 3: Added diagnostic code R10.2 Pelvic and perineal pain