Commissioning Policy

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Referral Guidelines:

Varicose Veins in the Legs

June 2017

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING SUMMARY

NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (also termed "the Commissioner" in this document) **will fund** the provision of specialist advice and surgery if clinically appropriate for patients with the following grades of varicose veins:

Grade III:	Varicose veins with complications, including bleeding, recurrent phlebitis or eczema
Grade IV:	Signs of venous insufficiency – lipodermatosclerosis or healed ulceration
Grade V:	Active leg ulceration

The CCG **does NOT fund** referral or surgical intervention for patients with lower grade varicose veins (grades 0, I and II); this includes patients with symptomatic but uncomplicated varicosities.

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Ratified by (name and date of Committee):	Commissioning Executive – April 2010, Policy Working Group December 2010 (minor) 1st April 2013 – this policy was formally adopted by: NHS South Worcestershire Clinical Commissioning Group NHS Redditch & Bromsgrove Clinical Commissioning Group NHS Wyre Forest Clinical Commissioning Group
Date issued:	August 2004, April 2007, December 2010, April 2013, June 2017
Internal Review Date:	Documents will be reviewed as a minimum every 3 years. However, earlier revisions to the policy may be made in light of published updates to local and national evidence of effectiveness and cost effectiveness and/or recommendations and guidelines from local, national and international clinical professional bodies. Date to Initiate Review: June 2020
Lead Executive/Director:	Chris Emerson, Programme Director
Name of originator/author:	Mrs Anita Roberts, Commissioning & Service Redesign Manager and Ms Chris Emerson, Head of Commissioning & Service Redesign – Original Document Mrs Helen Bryant & Mrs Fiona Bates – updates V2.0 and V3.0 Mrs Fiona Bates & Dr Emily Smith - updates V2.1
Target audience:	Patients, GPs, Secondary Care and Primary Care (Community) Providers, Independent Sector Providers
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Equality & Diversity Impact Assessment	Original - 12th November 2009, endorsed April 2010 Updated – 24th October 2016

Key individuals involved in developing the document:

Name	Designation	Version Reviewed
Mr Nicholas Hickey	Vascular Surgeon, Worcestershire Acute Hospitals NHS Trust	V1.0,
Ms Chris Emerson	Head of Acute Commissioning, NHSW, now Director of Elective Care FRP	All versions to date
Mrs Anita Roberts	Commissioning & Redesign, NHSW	V1.0
Mrs Helen Bryant	Commissioning & Redesign, NHSW, now Senior Commissioning Manager	V2.0 and V3.0
Emily Smith	FY2 Public Health, Worcestershire County Council	V3.0

Fiona Bates	Medicines Commissioning/Public Health Support, Worcestershire CCGs	V2.0 and V3.0
Mr Atwal	Vascular Surgeon, Worcestershire Acute Hospitals NHS Trust	V3.0

Circulated to the following individuals/groups for comments:

Name	Date
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	September 2015 November 2016 February/March 2017
Mr Atwal, Consultant Vascular Surgeon	August/September 2015, February/March 2017
Katie Osmond, Assistant Director of Finance and copied to All Vascular Surgeons at Worcestershire Acute Hospital Trust	October 2016 February/March 2017
Elective Care Clinical Review Group	March, April, June 2017

Version Control:

Version No	Type of Change	Date	Description of change
1.0	Policy Introduction	08/04	Policy development in full.
2.0	Minor changes	04/13	Update to reflect the changes to responsible commissioner arrangements in Worcestershire only
3.0	Update of policy	03/17	Updated/additional information in relation to: • Background and context • National guidance and facts • Evidence section Clarification around the grading scale Addition of referral proforma

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1. Definitions

1.1 **Varicose veins** are dilated, often palpable subcutaneous veins with reversed blood flow; they are most commonly found in the legs.

1.2 **Endothermal ablation** is the treatment of choice for varicose veins and involves the use of energy from either from high-frequency radio waves (radiofrequency ablation) or lasers (endovenous laser treatment) to seal the affected veins.

1.3 **Foam sclerotherapy** can also be used to treat varicose veins and involves the injection of special foam into the veins, which scars the veins and seals them closed.

1.4 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

1.5 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patients indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.6 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

1.7 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy

2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients for whom the Worcestershire CCGs have responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

2.3 This policy applies to patients presenting with symptoms of venous insufficiency. It is intended to assist GP's in making an appropriate decision to refer a patient with varicose veins for definitive treatment and to try and achieve consistency of referral. There is a finite budget available to treat varicose veins and GP assistance is sought to focus interventions on those patients with greatest clinical need and likelihood of benefit.

2.4 Pregnant women presenting with varicose veins are excluded from this policy; interventional treatment for varicose veins during pregnancy is not recommended other than in exceptional circumstances.

2.5 Patients presenting with varicose veins affecting other areas than the legs require confirmation of funding using the Individual Funding Request process.

2.6 Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, referral for Advice & Guidance should be considered as an alternative to a referral for clinical assessment.

2.7 There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria for surgery or is not considered clinically suitable for surgery. Such patients should be discharged without surgery.

2.8 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.

3. Background

3.1. The NHS Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3 Varicose veins are dilated, often palpable subcutaneous veins with reversed blood flow. They are most commonly found in the legs. Risk factors for developing varicose veins include advancing age, family history of venous disease, increased body mass index, smoking, sedentary lifestyle and pregnancy.

3.4 Estimates of the prevalence of varicose veins vary. Visible varicose veins in the lower limbs are estimated to affect at least a third of the population. Health Technology Assessment NHS R&D HTA Programme – Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial) estimated that the prevalence of visible varicose veins in Europe and the USA is approximately 25-30% for adult women and approximately 15% for men.

3.5 In some people varicose veins are asymptomatic or cause only mild symptoms, but in others they cause pain, aching or itching and can impact on their quality of life. Varicose veins may become more severe over time and can lead to complications such as changes in skin pigmentation, bleeding or venous ulceration. It is not known which people will develop more severe disease but it is estimated that 3–6% of people who have varicose veins in their lifetime will develop venous ulcers.

3.6 NHS treatment for varicose veins will concentrate on providing the most cost-effective solution for truncal vein incompetence, to reduce severe symptoms, treat complications and reduce the risk of further complications, NOT to provide a perfect cosmetic result. This approach will allow providers to treat as many patients as possible who have the greatest clinical need for intervention.

3.7 There are several options for the management of varicose veins, including:

- advice and reassurance
- conservative management (weight loss, exercise and leg elevation)
- compression hosiery
- interventional treatments (endothermal ablation, foam sclerotherapy and surgery)

Most patients with varicose veins can be managed in primary care with conservative management. This policy outlines which patients should be referred to a specialist vascular service and provides further definition of the grades/description of different severities.

4. Relevant National Guidance and Facts

4.1 The following information has been used to inform the development of this policy; any recommendations made by stated organisations do not necessarily apply to this policy. Please see section 6 for Patient Eligibility in accordance with this policy.

- **NICE Clinical Guidance 168 Varicose Veins in the legs (July 2013)**
- **NICE Support: Commissioning for Varicose Veins in the Legs (August 2014)**
- **The Royal College of Surgeons and Vascular Society Commissioning guide: Varicose veins (December 2013)**

4.2 Varicose Vein Grading

Description of grading for varicose veins varies from source to source but is generally in accordance with the following which, in increasing order of severity, will be used for the purpose of this policy:

Grade 0: Thread/Flare/Reticular veins
These are small red / blue venular flares. Reticular veins are easily visible small blue veins (less than 3mm diameter), not associated with large vein valvular incompetence. These may be unsightly but are of cosmetic concern only.

Grade I: Varicose veins without symptoms
Patients with truncal varicosities which may be associated with large vessel valvular incompetence but are asymptomatic.

Grade II: Uncomplicated varicose veins with symptoms such as pain, aching, heaviness or swelling in the absence of ulceration and/or skin changes
*This may be gross varicose veins that are asymptomatic or moderate veins that cause mild itching, mild oedema and/or mild aching **in the absense of ulceration and/or skin changes**.*

Grade III: Varicose veins with complications, including bleeding, recurrent phlebitis or eczema
Obvious thrombophlebitis, bleeding from varicose veins or present with objective evidence of venous hypertension – pitting oedema, lipodermatosclerosis or varicose eczema

Grade IV: Signs of venous insufficiency – lipodermatosclerosis or healed ulceration
This group includes healed varicose ulcers, inflamed lipodermatosclerosis, infected varicose eczema and severe extensive thrombophlebitis.

Grade V: Active leg ulceration

5. Evidence Review

The following reviews were undertaken to further inform the content of this policy:

Factors influencing Disease Progression and Response to Intervention

5.1 The evidence review undertaken to support the NICE Clinical Guideline was analysed to determine:

a. What proportion of people with varicose veins go on to develop ulceration
b. In patients with varicose veins, which signs/symptoms/patient characteristics are associated with disease progression
c. In people with leg varicose veins are there any factors that predict increased benefits or harms from interventional treatment

5.2 The available evidence in relation to the areas reviewed above was from small studies with limited quality, graded either low or very low in the NICE evidence summary. This makes it difficult to identify which symptomatic patient group is most likely to progress to complications and who is most likely to benefit from intervention. As part of guideline CG168, NICE make recommendations that further research be commenced to identify what factors influence the progression of varicose vein disease.

Recurrent Varicose Veins

5.3 A further review of the evidence informing the NICE clinical guideline sought to establish whether people with recurrent varicose veins:

a. are more likely to develop ulceration
b. have a better outcome following intervention (and if so, how do interventions compare)

5.4 This determined that:

- There is insufficient evidence with which to compare risks of ulceration or other negative outcomes/side effects of surgery in primary and recurrent varicose veins.
- The available evidence suggests that 10-30% of people who have treatment for varicose veins experience recurrence and those who experience recurrence of varicose veins post treatment are more likely to experience further recurrence (although there are no figures available to support this assumption).
- In terms of outcome of the treatment itself, there is very little evidence comparing the outcomes of those patients who had primary varicose veins against those who had had previous treatment.
- The lack of studies identifying patients with recurrent disease means that there is no data with which to compare the effect of different interventions in these patients.
- The NICE guideline concludes that "separate recommendations were not required" for people with recurrent varicose veins.

6. Patient Eligibility

6.1 Patient eligibility for referral and intervention is dependent on the grade of varicose veins that a patient has.

6.2 The table outlines the policy status for the different grades of varicose veins (whether primary or recurrent in nature):

<table>
<tr><th>Grade</th><th>Varicose Vein Description</th><th>Policy Status</th></tr>
<tr><td>0</td><td>Thread/Flare/Reticular veins</td><td rowspan="3">Referral & Surgical/Other Intervention NOT SUPPORTED
Conservative management recommended including where appropriate:
- light to moderate exercise (ankle flexion)
- daily elevation three or four times a day
- weight loss
Consideration may also be given to compression hosiery.</td></tr>
<tr><td>I</td><td>Varicose veins without symptoms</td></tr>
<tr><td>II</td><td>Uncomplicated varicose veins with symptoms such as pain, aching, heaviness or swelling in the absence of ulceration and/or skin changes</td></tr>
<tr><td>III</td><td>Varicose veins with complications, including bleeding, recurrent phlebitis or eczema</td><td rowspan="3">Referral & Surgical/Other Intervention is SUPPORTED

Notes:
1. Patients presenting with bleeding varicosities should be referred immediately
2. Patients waiting for an appointment are advised to engage in the conservative measures detailed above</td></tr>
<tr><td>IV</td><td>Signs of venous insufficiency – lipodermatosclerosis or healed ulceration</td></tr>
<tr><td>V</td><td>Active leg ulceration</td></tr>
</table>

Rationale:

a. *There is no good evidence to identify patients with symptomatic varicose veins whose condition might deteriorate and who should be prioritised for treatment in the absence of complications. Resources are limited and therefore priority is given to patients with greatest need.*
b. *Intervention in patients with identified symptoms and complications will treat the condition and limit development of further clinical problems.*

6.4 Interventional treatment should be in line with NICE guidance which identifies endothermal ablation as the first line intervention where suitable.

6.5 Providers are required to audit and report outcomes of intervention; ideally this should include all patients referred, the grade of varicose veins presenting, whether intervention was undertaken, the nature and outcome of intervention.

7. Supporting Documents

Worcestershire Clinical Commissioning Policy Collaborative: Varicose Vein Policy Review. July 2015.

Worcestershire Clinical Commissioning Policy Collaborative: Recurrent Varicose Veins. December 2016.

NICE Clinical Guideline CG 168: Varicose Veins: Diagnosis and Management. July 2013

Worcestershire CCGs: Operational Policy for Individual Funding Requests

Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services

NHS England: Ethical Framework for Priority Setting Resource Allocation

NHS England: Individual Funding Requests

NHS Constitution, updated 27th July 2015

8. Equality Impact Assessment

Organisation: Worcestershire CCGs

Department: Commissioning

Name of lead person: Fiona Bates

Piece of work being assessed: Varicose Vein Referral Guidelines

Aims of this piece of work: To define the circumstances when referral for consideration of varicose vein intervention is appropriate for patients in Worcestershire

Date of EIA: 24 October 2016

Other partners/stakeholders involved: CCPC (with PPI)

Who will be affected by this piece of work? Patients with signs and symptoms suggestive of varicose veins

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	There is some suggestion of greater prevalence following pregnancy so this would affect the female population but this does not affect the type of patient that intervention is available for. One small low quality study has identified male gender as an independent prognostic factor for ulceration but this would not impact on who is eligible for intervention.	No No
Race	None known	No
Disability	None known	No
Religion/ belief	None known	No
Sexual orientation	None known	No
Age	There may be an increased risk of disease progression with age which means that younger people will have less severe disease and will not be eligible for intervention. However if there disease severity merits intervention then this will be the same.	No
Social deprivation	Smoking, more prevalent in deprived populations, has been associated with ulceration but all patients with ulceration will be eligible for intervention	No
Carers	None known	
Human rights	None known	No

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead