

## 5 Planned de novo modelling

This section will specify modelling work prioritised by the GDG. It will provide details on how cost effectiveness will be considered for relevant, prioritised clinical areas/decision problems. Proposed modelling work should be listed in chronological order. For each decision model, please state the proposed analytical methods, relevant references and any comments on, for example, possible diversions from the reference case.

<i>Scope area<sup>a</sup> (clinical question(s)<sup>b</sup>)</i>	<i>Outline proposed analysis</i>
<p>Model 1 – Interventional therapies (If appropriate to intervene, which active treatment is cost-effective?)</p>	<p><b>Aim:</b> To determine the most cost-effective active treatment for varicose veins.</p> <p><b>Modelling method:</b> We will undertake a cost utility analysis based on a decision-analytic model. The model will comprise of a decision tree with a Markov model attached to each terminal node of the decision tree. The decision tree will depict ‘immediate’ clinical events/ outcomes occurring within 3 months after an intervention; and ‘intermediate’ events/ outcomes occurring 3 to 12 months after intervention. The Markov model will depict events that occur repeatedly over time, for example, the recurrence of reflux and varicosities and the need for further (re)treatments. In general, the Markov model will aim to capture ‘long-term’ events/ outcomes occurring after a year and beyond. We will consider the costs and health outcomes associated with retreatment of residual varicosities following sequential or concomittant phlebectomies, the complications of varicose veins and adverse events from intervention (for example, pulmonary embolism and venous thromboembolism, deep vein thrombosis and neurological events [stroke and nerve injury/damage]). The model will be set up to calculate, over the specified time horizon, the mean costs and QALYs gained by a cohort of people receiving the various forms of interventional therapy (or active treatments). Where evidence allows, we will consider the settings in which the interventions are performed, ie, whether they are delivered as day cases, in outpatient or inpatient settings; and/or whether they are performed under local or general anaesthesia. See below on interventions considered. The model will look</p>

<sup>a</sup> This should be the key areas relevant for considering opportunity costs and high priority for de novo modelling, as identified in section 3.

<sup>b</sup> Two or more questions may be addressed by a single analysis if appropriate.

separately at patients who require intervention to only one leg (unilateral treatment) and those that require intervention in both legs (bilateral treatment).

**Population:** People with primary or recurrent varicose veins.

**Perspective:** The analysis will be conducted from an NHS and personal social services perspective.

**Time horizon:** We will conduct the analysis over a lifetime horizon (or a time horizon long enough to capture all relevant costs and health outcomes).

**Cycle length:** As indicated above, the decision tree will capture 'immediate' events/ outcomes in the first 3 months and 'intermediate' events/ outcomes occurring over 3 to 12 months. The Markov model will have yearly cycles over a lifetime horizon (or a time horizon long enough to capture all relevant costs and health outcomes).

**Interventions considered:** Standard surgery (stripping plus ligation and phlebectomies), ultrasound-guided foam sclerotherapy, radiofrequency ablation, endovenous laser ablation, compression therapy and no treatment (lifestyle advice).

**Data sources:** Where possible, all inputs for the model will be taken from public sources. Probabilities of treatment success and other relevant clinical events will be taken from the clinical review conducted for this guideline. The clinical review may also serve as a useful source of data on resource use and health-related quality-of-life scores. Cost of interventions will be estimated from unit costs published in standard datasets including NHS Reference Costs, NHS Electronic Drug Tariff and the British National Formulary.

**Threshold and discounting:** As stipulated in the NICE Reference Case, we will work with a cost-effectiveness threshold of £20,000 per QALY gained in the base case and all future costs and health outcomes will be discounted at 3.5% per annum.

	<p><b>Sensitivity analysis:</b> Deterministic and probabilistic sensitivity analysis will be conducted to test the robustness of the economic results to variations in key parameters. This will include extending the base-case cost effectiveness threshold to £30,000 per QALY gained.</p>
<p>Model 2 – Interventional therapies (Stage of disease for intervention, and which active treatment is cost-effective at each stage?)</p>	<p><b>Aim:</b> To determine (i) at which stage of disease, is it cost effective to intervene rather than just offer conservative treatments; and (ii) at each stage of disease, which active treatment is cost effective.</p> <p><b>Modelling method:</b> We will undertake a cost utility analysis based on a decision-analytic model. The model will comprise of a decision tree with a Markov model attached to each terminal node of the decision tree. The decision tree will depict ‘immediate’ clinical events/ outcomes occurring within 3 months after an intervention; and ‘intermediate’ events/ outcomes occurring 3 to 12 months after intervention. The Markov model will depict events that occur repeatedly over time, for example, the recurrence of reflux and varicosities and the associated need for further (re)treatments. In general, the Markov model will depict ‘long-term’ events/ outcomes occurring after a year and beyond. We will consider the costs and health outcomes associated with retreatment of residual varicosities following sequential or concomitant phlebectomies, the complications of varicose veins and adverse events from intervention (for example, pulmonary embolism and venous thromboembolism, deep vein thrombosis and neurological events [stroke and nerve injury/damage]). The model will be set up to calculate, over the specified time horizon, the mean costs and QALYs gained by a cohort of people receiving the various types of interventional therapy (or active treatments). Where evidence allows, we will consider the settings in which the interventions are performed, ie, whether they are delivered as day cases, in outpatient or inpatient settings; and/or whether they are performed under local or general anaesthesia. See below on interventions considered. The model will look separately at patients who require intervention to only one leg (unilateral treatment) and those that require intervention in both legs (bilateral treatment).</p> <p><b>Population:</b> People with primary or recurrent varicose veins, subgrouped according to the CEAP classification system (specifically, groups C2, C3, C4, C5 and C6).</p> <p><b>Perspective:</b> The analysis will be conducted from an NHS and personal social services perspective.</p>

**Time horizon:** We will conduct the analysis over a lifetime horizon (or a time horizon long enough to capture all relevant costs and health outcomes).

**Cycle length:** As indicated above, the decision tree will capture 'immediate' events/ outcomes in the first three months and 'intermediate' events/ outcomes occurring over 3 to 12 months. The Markov model will have yearly cycles over a lifetime horizon (or a time horizon long enough to capture all relevant costs and health outcomes).

**Interventions considered:** Standard surgery (stripping plus ligation and phlebectomies), ultrasound-guided foam sclerotherapy, radiofrequency ablation, endovenous laser ablation, compression therapy and no treatment (lifestyle advice).

**Data sources:** Where possible, all inputs for the model will be taken from public sources. Probabilities of treatment success and other relevant clinical events will be taken from the clinical review conducted for this guideline. The clinical review may also serve as a useful source of data on resource use and health-related quality-of-life scores. Cost of interventions will be estimated from unit costs published in standard datasets including NHS Reference Costs, NHS Electronic Drug Tariff and the British National Formulary.

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**Sensitivity analysis:** Deterministic and probabilistic sensitivity analysis will be conducted to test the robustness of the economic results to variations in key parameters. This will include extending the base-case cost effectiveness threshold to £30,000 per QALY gained.