
Application 1166:
Final Decision
Analytic Protocol
(DAP) to guide the
assessment of
radiofrequency
ablation for the
treatment of varicose
veins due to chronic
venous insufficiency

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a draft decision analytic protocol that will be used to guide the assessment of an intervention for a particular population of patients. The draft protocol will be finalised after inviting relevant stakeholders to provide input to the protocol. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted “PICO” approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

Patients – specification of the characteristics of the patients in whom the intervention is to be considered for use;

Intervention – specification of the proposed intervention

Comparator – specification of the therapy most likely to be replaced by the proposed intervention

Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

Purpose of application

A proposal for an application requesting Medicare Benefits Schedule (MBS) listing of radiofrequency ablation (RFA) for the treatment of varicose veins due to chronic venous insufficiency was received from Covidien Pty Ltd by the Department of Health and Ageing in February 2011.

Intervention

Description

Venous return refers to flow of blood back to the heart. As blood returning to the heart from the legs must work against gravity, venous return of blood is achieved by a compression and release pumping action of the calf muscles, supported by elastic vein walls, and efficient one-way venous valves that prevent backflow of venous blood. Chronic venous disease (also known as chronic venous insufficiency) is a common disorder that impairs venous return. Pathophysiological abnormalities commonly evident in chronic venous disease are a loss of structural strength in the vein walls, damage to valves along the length of affected veins, or both (Fan 2003; Golledge & Quigley 2003). Elevated intravascular pressure is subsequently introduced into veins that are intended to function as a low-pressure system, resulting in retrograde blood flow termed venous reflux or venous insufficiency. This leads to pooling of blood, further damage to valves, and excessive distension, dilation and tortuosity of the vein.

The most common form of chronic venous disease is venous reflux within the great and small saphenous veins (known as the superficial venous system). In this case, incompetence in the perforator veins connecting the superficial and deep venous systems can enhance the problem by reducing or eliminating flow into the deep venous system, causing further stagnation of blood in the superficial veins. As the veins of the superficial system lack muscular support and lie close to the surface of the skin, they become visible with increased intravascular pressure, extending as venous reflux progresses through the insufficient vein. These varicosities, found most often on the calf or on the medial aspect of the leg between the groin and ankle, are commonly known as varicose veins. Visible varicose veins are one of the most prominent clinical signs of chronic venous insufficiency of the superficial venous system, and should be differentiated from more superficial telangiectases (commonly referred to as spider or thread veins) and reticular veins (NICE 2000).

The objective of radiofrequency ablation (RFA) for the treatment of varicose veins is the destruction or ablation of a refluxing vein or segment of vein, via application of thermal energy delivered through a radiofrequency catheter. The delivery of thermal energy directly to the vein wall leads to collagen denaturation, producing endothelial and vein wall damage, with eventual occlusion of the vein to abolish venous reflux (Manfrini et al 2000). To perform the RFA procedure, the affected leg is prepared and draped, and a superficial local anaesthetic agent is used to anesthetize the site of cannulation. Needle puncture of the vessel is guided by duplex ultrasonography. A guide wire is placed into the vessel, and an introducer sheath is passed over the guide wire, which is then removed. The catheter is passed through the sheath, with the tip advanced to just below the saphenofemoral or saphenopopliteal junction under duplex ultrasonography visualisation.

Compression is applied to the leg to exclude blood flow from the superficial venous system. The radiofrequency generator is then activated, with the resultant thermal energy applied as the sheath and catheter are progressively withdrawn until the entire vein is treated. The generator monitors the therapeutic vein wall temperature of 85°C ($\pm 3^\circ\text{C}$), with the catheter to be withdrawn at 2.5 to 3.0 cm/min (Manfrini et al 2000). Once the vein has been occluded, blood flow to the heart reroutes to the deep venous system of the legs (provided this system is competent and obstruction-free), and over time varicose veins and accompanying symptoms recede.

Administration, dose, frequency of administration, duration of treatment

Radiofrequency ablation is designed as a single-use therapeutic intervention, delivered as a single course of treatment per affected leg to obliterate the great or small saphenous veins through the application of thermal energy. While generally indicated for primary varicose veins, re-treatment of varicose veins with RFA may be possible in some patients where neovascularisation or revascularisation has occurred.

The equipment required for RFA is not restrictive, and the procedure is generally performed in an outpatient setting, such as a physician's rooms, without the need for an operating room or general anaesthesia. Patients will generally be referred for treatment by their general practitioner to an appropriate treating physician, such as an interventional radiologist, general surgeon, vascular surgeon, phlebologist, or vascular physician. At present no specific accreditation is required to perform RFA, although practitioners performing the procedure should have appropriate training in the use of ultrasound, as well as in the performance of peripheral endovascular therapies (as outlined by the Royal Australasian College of Surgeons). RFA would only be rebated if it is delivered by the service provider, and would not be referred for delivery by another health professional.

Co-administered interventions

As previously described, the patient would under normal conditions be referred to a treating physician. Both a pre- and post-procedural consultation with the physician would be required. Duplex scanning (MBS items 55236 and 55296 as defined in Table 1) is required at the pre-procedural consultation to confirm and map all areas of venous reflux within the individual to devise an appropriate treatment plan. It is used during the RFA procedure for the guidance of needle puncture of the vessel and appropriate placement of the RFA catheter within the vessel. And although follow-up protocols vary, duplex scanning is required at one or potentially more post-procedural consultations to assess venous occlusion and clinical results of RFA treatment. Duplex scanning is usually performed in the physician's rooms.

Upon completion of the RFA procedure, the site of venous puncture is dressed, and compression stockings and/or bandages are applied as appropriate to reduce the risk of venous thromboembolism and to reduce postoperative bruising and tenderness. Non-steroidal anti-inflammatory drugs are commonly used for post-procedural pain relief. For most patients additional procedures such as sclerotherapy or phlebectomy are required for the treatment of superficial veins below the knee, any tributary varicose veins, and telangiectases; these procedures are often performed in conjunction with the RFA procedure or in one or two follow-up sessions.

Background

Current arrangements for public reimbursement

Although not currently MBS listed, RFA for the treatment of varicose veins is performed widely in Australia. It is an outpatient procedure that can be conducted in hospital, medical centre or private clinic settings as the procedure does not require an operating room or general anaesthesia.

The current arrangements for reimbursement of the RFA procedure itself are paid for out-of-pocket by the patient. Under this arrangement, pre- and post-procedural consultations (including duplex scanning and post-procedural treatments such as sclerotherapy and phlebectomy) are covered by MBS item numbers and also captured by the Medicare Safety Net. No reimbursement is currently provided by private health insurers for RFA treatment.

Table 1 describes the current MBS items related to the treatment of varicose veins, including item numbers, corresponding item fee, and the number of claims made to the MBS from July 2010 to June 2011 for each. Interventions currently listed on the MBS for the treatment of varicose veins include:

- Sclerotherapy
- Phlebectomy
- Surgical ligation of the great and/or small saphenous vein
- Surgical stripping of the great and/or small saphenous vein
- Endovenous laser therapy (ELT)

It is important to note that ELT is an endovenous intervention for varicose veins that, like RFA, uses occlusion of saphenous veins as a mechanism for treatment.

Table 1: Current MBS-listed items related to treatment of varicose veins

Procedure	MBS Item Number	MBS Listing	MBS claims (Jun 2010 – Jul 2011) ^a
<i>Therapeutic procedures</i>			
Sclerotherapy	32500	VARICOSE VEINS where varicosity measures 2.5mm or greater in diameter, multiple injections of sclerosant using continuous compression techniques, including associated consultation - 1 or both legs - not being a service associated with any other varicose vein operation on the same leg (excluding after-care) - to a maximum of 6 treatments in a 12-month period Fee: \$105.65	56,302
	32501	VARICOSE VEINS where varicosity measures 2.5mm or greater in diameter, multiple injections of sclerosant using continuous compression techniques, including associated consultation - 1 or both legs - not being a service associated with any other varicose vein operation on the same leg (excluding after-care) where it can be demonstrated that truncal reflux in the long or short saphenous veins has been excluded by duplex examination - and that a 7th or subsequent treatment (including any treatments to which item 32500 applies) is indicated in a 12-month period Fee: \$105.65	0
Phlebectomy	32504	VARICOSE VEINS, multiple excision of tributaries, with or without division of 1 or more perforating veins - 1 leg - not being a service associated with a service to which item 32507, 32508, 32511, 32514 or 32517 applies on the same leg Fee: \$257.50	3,754

Procedure	MBS Item Number	MBS Listing	MBS claims (Jun 2010 – Jul 2011) ^a
Surgical ligation and/or stripping	32508	VARICOSE VEINS, complete dissection at the saphenofemoral OR saphenopopliteal junction - 1 leg - with or without either ligation or stripping, or both, of the long or short saphenous veins, for the first time on the same leg, including excision or injection of either tributaries or incompetent perforating veins, or both Fee: \$513.40	7,348
	32511	VARICOSE VEINS, complete dissection at the saphenofemoral AND saphenopopliteal junction - 1 leg - with or without either ligation or stripping, or both, of the long or short saphenous veins, for the first time on the same leg, including excision or injection of either tributaries or incompetent perforating veins, or both Fee: \$763.25	693
	32514	VARICOSE VEINS, ligation of the long or short saphenous vein on the same leg, with or without stripping, by re-operation for recurrent veins in the same territory - 1 leg - including excision or injection of either tributaries or incompetent perforating veins, or both Fee: \$891.65	1,483
	32517	VARICOSE VEINS, ligation of the long and short saphenous vein on the same leg, with or without stripping, by re-operation for recurrent veins in either territory - 1 leg - including excision or injection of either tributaries or incompetent perforating veins, or both Fee: \$1148.20	441
Endovenous laser therapy	32520	VARICOSE VEINS, abolition of venous reflux by occlusion of a primary or recurrent great (long) or small (short) saphenous vein of one leg (and major tributaries of saphenous veins as necessary), using a laser probe introduced by an endovenous catheter, including all preparation and immediate clinical aftercare but not including radiofrequency diathermy or radiofrequency ablation Fee: \$523.65	New item; data not available
	32522	VARICOSE VEINS, abolition of venous reflux by occlusion of a primary or recurrent great (long) and small (short) saphenous vein of one leg (and major tributaries of saphenous veins as necessary), using a laser probe introduced by an endovenous catheter, including all preparation and immediate clinical aftercare but not including radiofrequency diathermy or radiofrequency ablation Fee: \$778.50	New item; data not available
<i>Diagnostic imaging services</i>			
Duplex scanning	55236	DUPLEX SCANNING, unilateral, involving B mode ultrasound imaging and integrated Doppler flow spectral analysis and marking of veins in the lower limb below the inguinal ligament prior to varicose vein surgery, not being a service associated with a service to which an item in Subgroups 1 (with the exception of items 55026 and 55054), 3 or 4 of this Group applies - including any associated skin marking Fee: \$55.55	New item; data not available
	55296	DUPLEX SCANNING, unilateral, involving B mode ultrasound imaging and integrated Doppler flow spectral analysis and marking of veins in the lower limb below the inguinal ligament prior to varicose vein surgery, not being a service associated with a service to which an item in Subgroups 1 (with the exception of item 55054), 3 or 4 of this Group applies - including any associated skin marking Fee: \$111.05	4,236

MBS: Medicare Benefits Schedule

^a Claims data retrieved August 2, 2011 from: https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml

NOTE: Endovenous laser therapy to be included on Medicare Benefits Schedule in November 2011

Regulatory status

There are only three devices currently approved by the Therapeutic Goods Administration for use in treating varicose veins with RFA. Details on their listing on the Australian Register of Therapeutic Goods are provided in Table 2.

Table 2: Australian Register of Therapeutic Goods listings for radiofrequency ablation treatment of varicose veins

ARTG number	Sponsor name	ARTG label name	Approval date	Intended purpose
165437	Covidien Pty Ltd	VNUS RF Generator (model RFG2) – electrosurgical unit, general-purpose	21/9/2009	Intended for use with radiofrequency devices intended for vessel and tissue coagulation. The RF Generator measures and displays RF output Power, load Impedance (not displayed for some devices), and elapsed time of RF delivery. The RF Generator also interfaces with a sensor in the Device to provide a continuous display of measured Temperature during RF delivery.
165951	Covidien Pty Ltd	ClosureFAST catheter – catheter, intravascular, peripheral	9/10/2009	Intended for endovascular coagulation of blood vessels in patients with superficial vein reflux. The ClosureFAST catheter function is to provide thermal energy to the desired treatment site via RF heating of the catheter heating element and to relay temperature back to the RF generator. The catheter is connected to the RF generator via the cable connector.
166084	Covidien Pty Ltd	Stylet, catheter	14/10/2009	Intended for use in vessel and tissue coagulation including treatment of incompetent perforator and tributary veins.

ARTG: Australian Register of Therapeutic Goods; RF: radiofrequency

Patient population

Proposed MBS listing

Given the great deal of similarity in the two treatments, the prospective MBS item descriptor for RFA will be the same as for ELT, with minor modifications as appropriate (e.g. item fee). The proposed MBS item descriptor for RFA treatment of either the great or small saphenous vein (equivalent to surgical ligation/stripping MBS item 32508) is listed in Table 3.

Table 3: Proposed Medicare Benefits Schedule item descriptor for radiofrequency ablation for the treatment of varicose veins (great or small saphenous vein)

Category3 – Therapeutic Procedures
<p>MBS 325xx</p> <p>VARICOSE VEINS, abolition of venous reflux by occlusion of a primary or recurrent great (long) or small (short) saphenous vein of one leg (and major tributaries of saphenous veins as necessary), using a radiofrequency catheter introduced by an endovenous catheter, including all preparation and immediate clinical aftercare (including excision or injection of either tributaries or incompetent perforating veins, or both).</p> <p>(Anaes.)</p> <p>Fee: To be confirmed</p> <p>Explanatory notes:</p> <ul style="list-style-type: none"> It is recommended that the medical practitioner performing the radiofrequency ablation (RFA) has successfully completed a substantial course of study and training in the management of venous disease, which has been endorsed by their relevant professional organisation. RFA is recommended in cases where it is documented by duplex ultrasound that the great or small saphenous vein (or one of its major tributaries) demonstrates reflux of 0.5 seconds or longer.

A second MBS item relating to the RFA treatment of both the great and small saphenous veins (equivalent to surgical ligation/stripping MBS item 32511) is also proposed. The descriptor for this item is listed in Table 4.

Table 4: Proposed Medicare Benefits Schedule item descriptor for radiofrequency ablation for the treatment of varicose veins (great and small saphenous vein)

Category3 – Therapeutic Procedures
<p>MBS 325xx</p> <p>VARICOSE VEINS, abolition of venous reflux by occlusion of a primary or recurrent great (long) and small (short) saphenous vein of one leg (and major tributaries of saphenous veins as necessary), using a radiofrequency catheter introduced by an endovenous catheter, including all preparation and immediate clinical aftercare (including excision or injection of either tributaries or incompetent perforating veins, or both).</p> <p>(Anaes.)</p> <p>Fee: To be confirmed</p> <p>Explanatory notes:</p> <ul style="list-style-type: none"> • It is recommended that the medical practitioner performing the radiofrequency ablation (RFA) has successfully completed a substantial course of study and training in the management of venous disease, which has been endorsed by their relevant professional organisation. • RFA is recommended in cases where it is documented by duplex ultrasound that the great or small saphenous vein (or one of its major tributaries) demonstrates reflux of 0.5 seconds or longer.

The item fee for RFA will be determined by the Department of Health and Ageing, guided by the economic evaluation conducted during consideration of RFA for MBS approval. As a point of reference, the item fee for ELT is \$523.65 for treatment of the great or small saphenous vein, and \$778.50 for treatment of the great and small saphenous veins. No Extended Medicare Safety Net benefits are payable for these two items, and it is assumed this would also be the case for RFA.

Clinical place for proposed intervention

Lower limb varicose veins are a very common disease affecting adults. If chronic and untreated, the associated venous insufficiency can progress to significant morbidity including pain, oedema, fatigue and limb swelling, thrombophlebitis, bleeding and skin ulceration. One or more of these symptoms and the presence of clinically demonstrated venous reflux are generally regarded as indications for intervention (Bradbury et al 1999). Prevalence rates for varicose veins have been reported in the general community of countries with similar ethnic composition to Australia, ranging from 6.8 to 39.7 per cent in men and from 24.6 to 39.0 per cent in women. In a 2004 health survey of the Australian population by the Australian Institute of Health and Welfare (AIHW), 2.3 per cent of all respondents reported varicose veins as a long-term condition, an estimated 440,000 people (AIHW 2004). Statistics from the AIHW National Hospital Morbidity Database report that there were 16,176 hospital admissions in the 2009/2010 financial year for the treatment of varicose veins of the lower extremities (ICD-10 Diseases I83.0, I83.1, I83.2, & I83.9).¹

A variety of therapies are available for treating varicose veins, depending on the severity of symptoms and the clinical assessment of the patient. Patients require a physical examination to determine the source of venous incompetency, ideally followed by a duplex scan examination to confirm presence of reflux (Wolf & Brittenden 2001). Symptom relief measures include exercise, weight loss, elevation of limbs, avoidance of long periods of time sitting or standing, and use of compression stockings (Beckman 2002). Sclerotherapy is an outpatient procedure done under local anaesthetic, and is the

¹ Retrieved August 9, 2011, from: <http://www.aihw.gov.au/hospitals-data-cube/?id=10737419429>

treatment of choice for telangiectases and smaller veins. Ultrasound-guided sclerotherapy allows sclerosant to be injected directly into the great saphenous vein to treat larger and deeper varicosities (Beale and Gough 2005). However, there is doubt over the effectiveness of sclerotherapy where reflux has been demonstrated to be the cause of vascular insufficiency (Jakobsen 1979, Bergan et al 2001) or for treatment of large veins greater than 4 mm in diameter (Sadick 2005). Non-refluxing varicose veins on the surface of the leg, not including the saphenous veins, may be treated as an outpatient procedure under local anaesthetic using ambulatory phlebectomy (Bergan et al 2001). However, recurrence rates can be high if the source of the reflux is not treated (Sadick 2005).

Surgical ligation/stripping, ELT and RFA are indicated for treatment of the same general population: patients in whom the great and/or small saphenous veins have reflux or incompetence demonstrated on duplex scanning, and varicose vein symptoms significantly impinge on quality of life. These patients have exhausted conservative treatment measures, and sclerotherapy is considered unlikely to provide successful results. Based on current usage of surgical ligation/stripping (Table 1), the potential number of patients suitable for treatment of primary varicose veins with surgery, ELT, or RFA could be approximately 8,000 per year (MBS items 32508 and 32511), while approximately 2,000 more patients per year could be suitable for surgery, ELT or RFA treatment of recurrent varicose veins (MBS items 32514 and 32517).

There is potential for demand for the treatment of varicose veins to increase due to additional and perceived health benefits, and the wider availability, of less invasive treatments such as ELT and RFA. However, it is anticipated that almost all of this increase will occur as a result of the MBS listing of ELT. As RFA acts as a direct alternative to ELT and surgical ligation/stripping, MBS listing of RFA will have minimal impact on the current management of varicose veins, and it is not anticipated that this listing will increase demand. The demand for RFA treatment of recurrent varicose veins caused by neovascularisation or revascularisation is anticipated to be similar to that for ELT.

Figure 2a illustrates the current clinical management algorithm for diagnosing and treating patients with varicose veins in the absence of RFA, while Figure 2b shows the management algorithm for diagnosing and treating varicose veins should RFA be reimbursed as requested.

Figure 2a: Clinical management algorithm for diagnosis and treatment of varicose veins in the absence of radiofrequency ablation

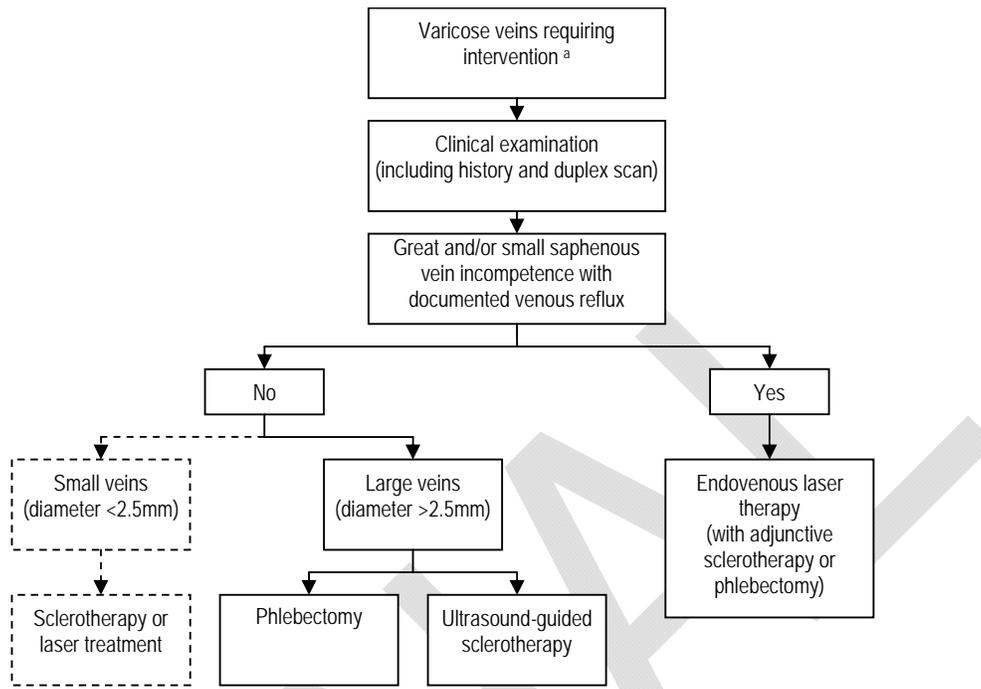
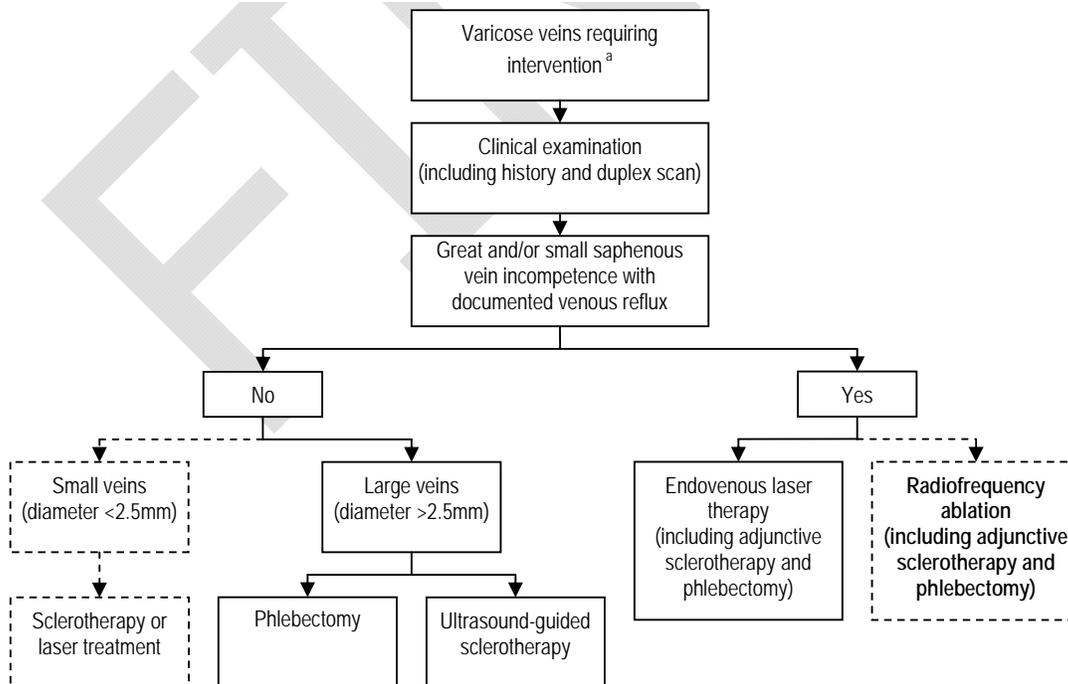


Figure 2b: Clinical management algorithm for diagnosis and treatment of varicose veins should radiofrequency ablation be reimbursed as requested



^a Indication for treatment includes exhaustion of conservative treatment measures, significant symptoms, and the presence of venous reflux

^b To be included on Medicare Benefits Schedule in November 2011

NOTE: Dashed lines represent procedures not currently covered by the Medicare Benefits Schedule

Comparator

Due to the similarities between the two procedures, ELT (MBS items 32520 and 32522) provides the most appropriate comparator to inform the comparative effectiveness and cost-effectiveness of RFA. The two treatments are indicated for the same patient population, and are essentially identical except for the use of different specialised capital equipment and catheters, with thermal energy delivered through either a radiofrequency catheter or laser fibre. The objectives of the two treatments are the same, being the destruction or ablation of a refluxing vein or segment of vein via application of thermal energy. The procedure to place the laser fibre within the vein is the same as for RFA, also conducted under duplex ultrasonography guidance. The physiological mechanism of vein ablation is also the same, with thermal energy producing endothelial and vein wall damage, denaturing and occluding the vein to close the vein, abolishing venous reflux and visible varicosities.

Duplex scanning (MBS items 55236 and 55296) is also required prior to, during, and following the ELT procedure, for the same purposes as described for RFA. As for RFA, capital costs of generators and disposables (i.e. laser fibres) are considerable, and although usually an inpatient procedure, resources related to day theatre usage and attending nursing staff should also be considered. Post-treatment sclerotherapy and/or phlebectomy are also required in the majority of cases to treat veins below the knee, tributary varicose veins, and telangiectases. However, post-treatment requirements are assumed to be the same for ELT and RFA treatment.

Clinical claim

Radiofrequency ablation for varicose veins is proposed to provide a clinical improvement on the currently MBS-funded procedure of ELT, for which severe pain can occur approximately ten days post-procedure that requires an ultrasound examination in order to eliminate the possibility of blood clot formation; this does not occur after treatment with RFA. The overall clinical claim for RFA is that it is non-inferior to ELT in terms of safety, effectiveness and cost-effectiveness. If the assessment concludes that there is any uncertainty around this claim, an evaluation of this uncertainty will be provided by presentation of a cost-effectiveness or cost-utility analysis. However, a cost-minimisation analysis may be deemed appropriate if the assessment clearly demonstrates that RFA is no worse than ELT in terms of both effectiveness and safety (see Table 5 for details).

Table 5: Classification of an intervention for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator					
		Superior		Non-inferior	Inferior		
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA		Net clinical benefit	CEA/CUA
						Neutral benefit	CEA/CUA ^a
						Net harms	None ^b
	Non-inferior	CEA/CUA		CEA/CUA ^a		None [^]	
	Inferior	Net clinical benefit	CEA/CUA	None ^b		None [^]	
		Neutral benefit	CEA/CUA ^a				
Net harms		None ^b					

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

^a May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^b No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes

The clinical safety and effectiveness outcomes related to RFA are similar to ELT. Clinical effectiveness outcomes of interest for the two treatments may include, but are not limited to:

- Abolition of reflux (primary effectiveness outcome)
- Recanalisation, neovascularisation and recurrence
- Reduction of symptoms
- Quality of life
- Time taken to resume normal activities

Potential clinical safety outcomes and adverse events related to ELT and RFA may include, but are not limited to:

- Pulmonary embolism
- Deep venous thrombosis
- Superficial thrombophlebitis
- Nerve injuries
- Paraesthesia
- Infection / cellulitis
- Haematoma
- Ecchymosis / bruising
- Skin burns
- Post-procedural pain
- Phlebitis
- Induration
- Hyperpigmentation / dyschromia

Health care resources

Details on the health care resources whose utilisation is likely to be impacted should RFA be made available as requested are listed below in Table 6.

Table 6: List of resources to be considered in the economic evaluation

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets	Other govt. budgets (PBS, hospitals, etc.)	Private health insurer	Patient	Total cost
<u>Resources provided to identify eligible population should intervention be made available as proposed</u>										
- Duplex scanning (planning)	Sonographer	Consultant's rooms	100%	1	\$94.40		\$0.00	\$0.00	\$16.65	\$111.05
<u>Resources provided to deliver proposed intervention</u>										
- RFA	Vascular surgeon	Consultant's rooms	100%	1	\$515.10	\$0.00 ^a	\$0.00	\$0.00	\$90.90	\$606.00 ^b
<u>Resources provided in association with proposed intervention (e.g., pre-treatments, co-administered interventions, resources used to monitor or in follow-up, resources used in management of adverse events, resources used for treatment of down-stream conditions)</u>										
- Duplex scanning (guidance)	Sonographer	Consultant's rooms	100%	1	\$94.40		\$0.00	\$0.00	\$16.65	\$111.05
- Duplex scanning (confirmation)	Sonographer	Consultant's rooms	100%	1	\$94.40		\$0.00	\$0.00	\$16.65	\$111.05
<u>Resources provided to identify eligible population in current scenario</u>										
- Duplex scanning (planning)	Sonographer	Consultant's rooms	100%	1	\$94.40		\$0.00	\$0.00	\$16.65	\$111.05
<u>Resources provided to deliver comparator 1</u>										
- ELT	Vascular surgeon	Consultant's rooms	100%	1	\$515.10	\$0.00 ^a	\$0.00	\$0.00	\$90.90	\$606.00 ^b
<u>Resources provided in association with comparator 1</u>										
- Duplex scanning (guidance)	Sonographer	Consultant's rooms	100%	1	\$94.40		\$0.00	\$0.00	\$16.65	\$111.05
- Duplex scanning (confirmation)	Sonographer	Consultant's rooms	100%	1	\$94.40		\$0.00	\$0.00	\$16.65	\$111.05

ELT: endovenous laser therapy; MBS: Medicare Benefits Schedule; PBS: Pharmaceutical Benefits Scheme; RFA: radiofrequency ablation

^a No Extended Medicare Safety Net benefits will be payable for this item

^b Fee provided by applicant; no calculations were provided, only the statement that the cost of RFA would be the same as for ELT

Other potentially relevant health care resources related to RFA such as day theatre usage, attending nursing staff, and potential follow-up procedures (e.g. compression stockings and bandaging, phlebectomy, sclerotherapy) will be common to both RFA and ELT.

Proposed structure of economic evaluation (decision-analytic)

The PICO criteria proposed for the comparison of RFA and ELT are provided in Table 7.

Table 7: Summary of PICO to define research question that assessment will investigate

Patients	Intervention	Comparator	Outcomes
Patients with varicose veins with reflux of the great and/or small saphenous vein, as demonstrated by ultrasound	Radiofrequency ablation for the treatment of saphenous vein reflux	Endovenous laser therapy for the treatment of saphenous vein reflux	<p>Effectiveness (including but not limited to):</p> <ul style="list-style-type: none"> • Abolition of reflux (<i>primary effectiveness outcome</i>) • Recanalisation, neovascularisation and recurrence • Reduction of symptoms • Quality of life • Time taken to resume normal activities <p>Safety (including but not limited to):</p> <ul style="list-style-type: none"> • Pulmonary embolism • Deep venous thrombosis • Superficial thrombophlebitis • Nerve injuries • Paraesthesia • Infection / cellulitis • Haematoma • Ecchymosis / bruising • Skin burns • Post-procedural pain • Phlebitis • Induration • Hyperpigmentation / dyschromia

Clinical research questions for public funding:

1. What is the safety of radiofrequency ablation as a treatment for varicose veins with saphenous reflux demonstrated by ultrasound, compared to endovenous laser therapy?
2. What is the effectiveness of radiofrequency ablation as a treatment for varicose veins with saphenous reflux demonstrated by ultrasound, compared to endovenous laser therapy?
3. What is the cost-effectiveness of radiofrequency ablation as a treatment for varicose veins with saphenous reflux demonstrated by ultrasound, compared to endovenous laser therapy?

Decision analytic diagram

A decision analytic diagram was deemed unnecessary for this assessment, due to the treatment pathways for RFA and ELT being considered to be identical.

References

- AIHW (2004). Australian Institute of Health and Welfare. *Australia's Health 2004*. Canberra, Australia.
- Beale RJ & Gough MJ (2005). Treatment options for primary varicose veins – a review. *European Journal of Vascular and Endovascular Surgery*, 30(1): 83–95.
- Beckman JA (2002). Diseases of the veins. *Circulation*, 106(17): 2170-2172.
- Bergan JJ, Sparks SR et al (2001). Growing the vascular surgical practice: Venous disorders. *Cardiovascular Surgery*, 9(5), 431-435.
- Bradbury A, Evans C et al (1999). What are the symptoms of varicose veins? Edinburgh vein study cross sectional population survey. *British Medical Journal*, 318(7180): 353-356.
- Fan CM (2003). Epidemiology and pathophysiology of varicose veins. *Techniques in Vascular and Interventional Radiology*, 6(3): 108-110.
- Golledge J & Quigley FG (2003). Pathogenesis of varicose veins. *European Journal of Vascular and Endovascular Surgery*, 25(4): 319-324.
- Jakobsen BH (1979). The value of different forms of treatment for varicose veins. *British Journal of Surgery*, 66(3): 182–184.
- Manfrini S, Gasbarro V et al (2000). Endovenous management of saphenous vein reflux. *Journal of Vascular Surgery*, 32(2): 330-342.
- NICE (2000). National Institute for Clinical Excellence. *Referral advice: a guide to appropriate referral from general to specialist services* [internet]. Retrieved August 15, 2011, from: <http://www.nice.org.uk/media/94D/BE/Referraladvice.pdf>
- Sadick ND (2005). Advances in the treatment of varicose veins: ambulatory phlebectomy, foam sclerotherapy, endovascular laser, and radiofrequency closure. *Dermatologic Clinics*, 23(3): 443-455.
- Wolf B & Brittenden J (2001). Surgical treatment of varicose veins. *Journal of the Royal College of Surgeons of Edinburgh*, 46(3): 154-158.