Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1166 - Radiofrequency ablation for the treatment of varicose veins due to chronic venous insufficiency

Applicant: Covidien Pty Ltd
Date of MSAC consideration: 2 August 2012

1. Purpose of application

In February 2011, an application was received from Covidien Pty Ltd, requesting Medicare Benefits Schedule (MBS) listing of radiofrequency ablation (RFA) for treatment of varicose veins due to chronic venous insufficiency.

2. Background

MSAC has not previously assessed RFA for treatment of varicose veins due to chronic venous insufficiency.

3. Prerequisites to implementation of any funding advice

MSAC noted that there were three devices currently approved by the Therapeutic Goods Administration for use in treating varicose veins with RFA when the Decision Analytic Protocol (DAP) was made final in January 2012.

4. Proposal for public funding

Two MBS items were proposed by the applicant that are equivalent to MBS items 32520 and 32522 for endovenous laser therapy (ELT).

5. Consumer Impact Statement

The submission-based assessment report considered by MSAC stated that patients will benefit from RFA being listed on the MBS because:

- it provides an alternative not currently available to them;
- it will reduce the risk of post-operative pain and bruising;
- patients will experience improvements in quality of life associated with a reduction in this pain and bruising; and
- there will be less-out-of pocket expenses for delivery of the service, and lower costs associated with post-operative pain management and follow-up.

6. Proposed intervention's place in clinical management

RFA was proposed as a direct alternative to ELT and surgical vein ligation/stripping.
For RFA treatment, patients require a physical examination to determine the source of venous incompetence, ideally followed by a duplex scan examination to confirm presence of reflux.

RFA or ELT (with sclerotherapy and phlebectomy where required) are then indicated for patients who have exhausted conservative treatment measures, and sclerotherapy alone is considered unlikely to provide successful results.
The Final DAP indicated that 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. These post-treatment requirements are assumed to be the same for ELT and RFA treatment.
To simplify the clinical management algorithms in relation to RFA and its comparator (ELT), surgical vein stripping was not included. This was agreed upon by the Protocol Advisory Sub Committee (PASC) in their advice and finalisation of the DAP.

7. Other options for MSAC consideration

MSAC noted that PASC agreed sclerotherapy and/or phlebectomy performed at the same time as RFA should be included in the MBS service (as is the case for surgical ligation/ stripping - MBS items 32508 and 32511). MSAC also noted that the Department of Health and Ageing is currently progressing re-wording of ELT MBS items 32520 and 32522 so that sclerotherapy and/or phlebectomy is part of an ELT MBS service. This will prevent other varicose vein items (for sclerotherapy and phlebectomy) being billed at the same time as ELT.

8. Comparator to the proposed intervention

MSAC accepted that endovenous laser therapy (ELT) is the appropriate comparator, agreeing with its Evaluation Sub-Committee (ESC) that RFA is a clear substitute for ELT and not an adjunct service. MSAC noted that ELT has been MBS listed since 1 November 2011, through MBS item numbers 32520 and 32522.

9. Comparative safety

MSAC concluded that, from the evidence available, RFA is possibly safer and more effective in the short term than ELT for some health outcomes. For example, RFA appears to cause less post-procedural pain and bruising up to the two week mark than ELT. MSAC considered that this was plausible because RFA uses radiofrequency waves to heat the vein whereas ELT uses laser energy which boils the blood. MSAC also agreed that this explains why RFA poses a lesser risk than ELT of inadvertently perforating the treated vein.

10. Comparative effectiveness

MSAC concluded that, from the evidence available, RFA is no worse than ELT in the more patient-relevant effectiveness and safety outcomes of abolition of vein reflux at six months, recanalization, neo-vascularisation, recurrence rates, infection rates, long-term reduction of symptoms, long-term quality of life and time taken to resume normal activities. Thus MSAC judged from these data that RFA does not retain any long-term health outcome advantage over ELT, but that, in the absence of comparative data beyond 12 months, there remains some uncertainty with this judgement.

11. Economic evaluation

MSAC noted that a cost minimisation analysis was conducted, proposing the same MBS fee for RFA as currently applies for ELT, and agreed that this was appropriate based on the evidence presented for both RFA and ELT.

MSAC noted advice from its Evaluation Sub Committee that anticipated reductions in pain and bleeding, and lower complication rates, may result in more patients seeking treatment than before, thus generating an overall increase in demand.

MSAC was advised that the fees currently being charged for ELT range from $800 to $6000, and that ELT is predominantly conducted in the out of hospital setting. MSAC noted that this

practice has resulted in varying out of pocket costs for patients receiving ELT, with a median of out of pocket costs of approximately $1,600 per patient.

12. Financial/budgetary impacts

MSAC acknowledged that the Department of Health and Ageing is currently in the process of conducting a broader review of all varicose vein items, which will include ELT items and will encompass the financial impact of all these procedures on the MBS.
MSAC observed that the economic analysis focussed on the MBS fee and did not reflect the out-of-pocket consequences for patients of the significantly higher actual fees likely to be charged for RFA.

In view of this, MSAC advised that RFA would have similar consequences for the Extended Medicare Safety Net (EMSN) as ELT, and so capping should also apply to RFA consistent with what is already in place for ELT.

13. Key Issues for MSAC

MSAC noted that patient out-of pocket expenses had not been estimated by the assessment or critique, and that long term costs of treatment are uncertain given that long-term treatment failure and re-treatment rates are unknown.

MSAC considered advice that the listing of RFA may increase overall demand for varicose vein treatment by around 20% by virtue of offering patients an additional treatment option, rather than RFA substituting for ELT within the current projected growth in demand.

14. Other significant factors

MSAC considered options proposed by its Evaluation Sub Committee on potential MBS item descriptors as follows:

- amend the second (higher rebated) proposed RFA item to fund a bilateral RFA service;
- Detail legally-enforceable training requirements within RFA descriptors; and
- Inserting within the RFA descriptors the requirement that reflux of 0.5 seconds or longer (within the great or small saphenous vein, as relevant) be documented by duplex ultrasound.

15. Summary of consideration and rationale for MSAC's advice

MSAC considered that the underlying medical condition of lower limb varicose veins is a specific condition associated with the great and or small saphenous vein/s incompetence, resulting in venous reflux causing engorgement and in the visible presence of the affected vein/s. If chronic and untreated, varicose veins/venous insufficiency can progress to significant morbidity including pain, oedema, fatigue and limb swelling, thrombophlebitis, bleeding and skin ulceration.

MSAC noted that the objective of RFA is the destruction (ablation) of a refluxing vein or segment, via the application of thermal energy delivered through a radio frequency catheter.

MSAC noted that RFA can be performed in the ambulatory care setting, with standard equipment and that, like ELT, ultrasound is central to the procedure. MSAC accepted that, with the correct training, this procedure can be performed by most procedurally orientated medical providers, with vascular surgeons, GP's, radiologists and cosmetic surgeons being most likely to provide this intervention.

MSAC discussed a number of medical interventions (and the costs associated with them) currently used for diagnosed chronic venous insufficiency of the saphenous venous tree, noting the following;

- Sclerotherapy - 1 Leg (MBS items 32500 and 32501) (fee $107.75)
- Phlebectomy - 1 Leg (MBS item 32504) (fee $262.65)
- Surgical dissection of the sapheno-popliteal and/or sapheno-femoral junction-by excision of or injection techniques (MBS items 32508 and 32511)
  - Great or small saphenous vein of one leg (fee $523.65) or
  - Great and small saphenous veins of one leg (fee $778.50)
- Endovenous Laser Therapy (ELT)
  - Great or small saphenous vein of one leg (fee $523.65) or
  - Great and small saphenous veins of one leg (fee $778.50)

MSAC considered that Sclerotherapy and Phlebectomy had an established place for small varicosities and telangiectasia rather than in the presence of reflux, and that early utilisation patterns suggested that ELT was being used to increase the overall number of varicose vein procedures rather than replacing surgical dissection. This increase raised the concern that ELT (and RFA) procedures would increasingly be used for the purposes of cosmesis. Accordingly, MSAC advised that clear definitions of eligible veins for RFA therapy couched in terms of reflux should be included in the item descriptor, and these definitions should also apply to ELT (see proposed MBS item descriptors below).

Even with this targeting of RFA (and ELT), MSAC advised that listing RFA on the MBS has the potential for increasing the utilisation of such services (surgical dissection, ELT and RFA) in relation to the treatment of varicose veins by 20% over surgical dissection and ELT alone.

MSAC agreed that this additional 20% would be more a reflection of the ability to offer patients another minimally invasive treatment option compared to the in-hospital surgical alternative.

16. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, effectiveness and cost effectiveness of radio frequency ablation (RFA) for the treatment of varicose veins of the lower limb/s due to chronic venous insufficiency, MSAC supports the public funding of ultrasound guided endoluminal RFA for this purpose at the same fees and with the same Extended Medicare Safety Net Cap as the corresponding ELT items.

MSAC advised that the MBS item descriptor should be along the following lines (which reflect the recent changes to the ELT item descriptor), and that the same definition of eligible varicose veins should also be applied to the current ELT MBS item descriptors:

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, where it is documented by duplex ultrasound that the great or small saphenous vein demonstrates reflux of 0.5 seconds or longer, including all preparation and immediate clinical aftercare (including excision or injection of either tributaries or incompetent perforating veins, or both), not provided on the same occasion as a service described in any of items 32500, 32501, 32504 or 32507of the General Medical Services Table.
Fee: $523.65

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, where it is documented by duplex ultrasound that the great and small saphenous vein demonstrates reflux of 0.5 seconds or longer, including all preparation and immediate clinical aftercare (including excision or injection of either tributaries or incompetent perforating veins, or both), not provided on the same occasion as a service described in any of items 32500, 32501, 32504 or 32507of the General Medical Services Table.
Fee: $778.50.

MSAC also advised that the note currently applying to ELT should also apply to RFA as follows:

- 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.

17. Applicant's Response to the Public Summary Document
Nil

18. Context for decision
This advice was made under the MSAC Terms of Reference.
MSAC is to:

- Advise the Minister for Health and Ageing on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:
  - the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
  - whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
  - the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
  - the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
  - other matters related to the public funding of health services referred by the Minister.
  - Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.
  - MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

19. Linkages to other documents
MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au