

Public Summary Document

Application No. 1344.1 – Podiatric Surgeons for access to a range of MBS numbers for surgery of the foot and ankle

Applicant: Australian College of Podiatric Surgeons

Date of MSAC consideration: MSAC 66th Meeting, 30-31 March 2016

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

The resubmission from the Australasian College of Podiatric Surgeons' seeks podiatric surgeons' access to certain MBS items for foot and ankle services. The Department received the resubmission on 11 December 2015.

Similar to the previous application, the resubmission proposed podiatric surgeons' access to 39 MBS items covering eight clinical conditions:

- Hallux abducto valgus;
- Hammer and claw toes;
- Hind foot/ankle pathology;
- Ingrown toenails;
- Hallux rigidus;
- Heel pain;
- Nerve impingement; and
- Tumour (benign)

It also sought MBS access to co-administered services such as imaging, pathology, anaesthesia, and referrals.

2. MSAC's advice to the Minister

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC did not support public funding of Podiatric Surgeons to access a range of MBS numbers for surgery of the foot and ankle. MSAC found there was a lack of evidence for comparative safety and effectiveness in relation to comparable services, and the clinical need remained uncertain.

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

MSAC noted that the proposed public funding of podiatric surgeons' access to 39 existing MBS items related to surgical treatments, services and consultations specific to foot and

ankle surgery was considered in April 2015. MSAC noted that it did not support public funding at the time due to uncertainty regarding the unmet need for podiatric surgeons' services, evidence of non-inferiority to orthopaedic surgeons, and podiatric surgeons' scope of practice. MSAC was concerned that the resubmission did not include new data addressing the podiatric surgeons' claims of non-inferiority to orthopaedic surgeons and that the applicant had not worked with the Department since the previous MSAC consideration to consider a discrete set of items relevant to their current scope of practice.

MSAC noted that although podiatric surgeons are skilled health care professionals, they currently do not practice in public settings which, unlike orthopaedic surgeons, may limit their exposure to more complex cases. MSAC reaffirmed that it was beyond the remit of the committee to comment on scope of practice or provide an assessment on competencies and accreditation standards of podiatric surgeons.

MSAC considered evidence regarding the clinical effectiveness of podiatric surgeons' services, as provided in the initial application, and noted that direct comparisons with orthopaedic surgeons could not be made given that, with one exception, none of the included studies were conducted in the same setting. MSAC noted that indirect comparisons were also difficult as most studies reported on disparate outcomes and no single outcome measure is preferred in the wider literature on ankle and foot clinical research.

MSAC considered new evidence presented in the resubmission to address uncertainty surrounding the unmet need for podiatric surgeons' services. MSAC noted that the evidence comprised the results of a telephone survey conducted with 10 orthopaedic surgeons to gauge wait times for appointments and procedures. Although the results indicated that wait times were longer for orthopaedic surgeons compared to podiatric surgeons, MSAC was concerned that the survey was not conducted independently, the representativeness of the sample of orthopaedic surgeons was uncertain and the comparability of the surgeons' case mix was also uncertain.

MSAC questioned whether the applicant's prediction of unmet need, based on the findings of the 2008 Access Economics report cited in the resubmission, was overstated given that it was not clear from this data how much of the projected demand would be covered by orthopaedic surgeons. MSAC was concerned that even if these predictions were accurate, podiatric surgeons would have insufficient capacity to meet this need.

MSAC emphasised that no new data was provided to support the applicant's claims of podiatric surgeons' non-inferiority to orthopaedic surgeons. MSAC noted that the resubmission did not attempt to update the literature review relevant to these claims from other countries. MSAC acknowledged that the podiatric surgeons' audit is a commendable initiative which demonstrates low complication rates. However, MSAC was concerned about continuing uncertainties related to the podiatric surgeons' case mix and in turn, the possibility that in private practice, they are exposed only to selected uncomplicated cases that are more likely to have better outcomes. MSAC also noted that the resubmission did not explore whether any audit data comparing podiatric surgeons and medically qualified surgeons working in the same setting in other countries has become available since the original application.

MSAC considered the testimonials provided in the reapplication and noted that while most were favourable towards the submission, the data was of low quality and its representativeness was uncertain. MSAC also considered the case studies presented in the reapplication and noted that although they illustrated how the intervention of podiatric

surgeons' could be beneficial, their usefulness was limited by the lack of long-term follow-up in the data.

MSAC noted that its request for the development of a discrete set of items had not resulted in a changed set of items in the applicant's resubmission. MSAC reiterated that the ratio of consultations to surgical services proposed by the applicant is high, with consultation services comprising 70% of total forecast services, noting that this indicates the potential for consultation items to be claimed for non-specified services. MSAC also expressed concern about continuing uncertainty as to whether podiatric surgeons cover the same range and complexity of cases as orthopaedic surgeons and whether they are able to provide the same level of service, particularly with regards to the management of patient complications.

MSAC noted that the cost analysis conducted by the applicant relies on an assumption of non-inferiority to orthopaedic surgeons which has not been established by the evidence presented in the reapplication. MSAC also noted that the financial and budgetary implications of podiatric surgeons' access to MBS items remained uncertain. This was primarily due to the fact that the provided estimates were highly dependent on the number of accredited podiatric surgeons over time and in turn, the number of patients they each would treat. MSAC remains concerned that MBS funding could result in increased numbers of trainee podiatric surgeons, with the potential to increase the number of services they provide and the associated costs as a consequence.

MSAC emphasised that the applicant needs to provide direct comparative evidence demonstrating the non-inferiority of podiatric surgeons to orthopaedic surgeons, both with regards to safety and efficacy. MSAC acknowledged that there is little high-level evidence comparing these two groups and agreed that orthopaedic surgeons may be reluctant to assist the applicant in generating this data given their previously noted opposition to the application. Therefore, MSAC recommended that the applicant considers published or unpublished data from international contexts where podiatric surgeons receive a similar level of training and work alongside orthopaedic surgeons, as is the case in the United Kingdom (UK) for example. MSAC noted that while this data may not necessarily be of high quality, it could still assist the applicant in substantiating their non-inferiority claim.

In addition, MSAC expressed uncertainty about the package of care delivered to patients as outlined by the applicant and was particularly concerned about the lack of evidence supporting podiatric surgeons' ability to provide pre- and post-operative care and to work in multidisciplinary teams. MSAC noted that in the absence of such evidence, the committee could not confidently state that patient health outcomes will not deteriorate as a consequence of podiatric surgeons accessing the proposed MBS items.

MSAC suggested that in conjunction to demonstrating non-inferiority of procedure to orthopaedic surgeons, the applicant would need to demonstrate that podiatric surgeons are able to work within multidisciplinary team environments and are capable of managing pre-and post-operative aspects of patient care, including complications. MSAC also suggested that the applicant considers evidence demonstrating the involvement of podiatric surgeons in multidisciplinary teams from international contexts (e.g. UK), given that there are currently no equivalent models of care in Australia. MSAC recommended that this evidence should be used by the applicant to build a case for the utility of podiatric surgeons' services within multidisciplinary teams. MSAC noted that this evidence may also encourage the applicant to trial a similar model in Australia. MSAC suggested that it would be helpful if podiatric surgeons could establish their role as part of a multidisciplinary teams in the public setting as a first step in generating Australian-specific data demonstrating the safety and effectiveness

of the care they provide and their capability in providing the surgery as well as ensuring preand post-operative patient management.

MSAC reinforced that the applicant should again consider a subset of the requested items where evidence of need and comparable safety and effectiveness with orthopaedic surgeons exists.

4. Background

Application 1344 was previously considered by MSAC in April 2015. MSAC did not support public funding due to uncertainty about:

- unmet need for podiatric surgeons' services;
- the evidence for podiatric surgeons' services non-inferiority to orthopaedic surgeons; and
- the application's scope of practice, as identified by the Protocol Advisory Subcommittee (PASC) and ESC.

MSAC recommended reconsideration of the application when the National Registration and Accreditation Scheme (NRAS) review was complete and the applicant had worked with the Department of Health to consider a discrete set of MBS items which are developed and prioritised according to current practice and level of risk.

The Public Summary Document is available at:

http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1344-public

5. Proposal for public funding

There was no change to the applicant's proposal considered in April 2015.

The resubmission noted that the list of MBS item numbers requested was developed in consultation with the Department of Health during the development stages of the Application and is based upon both current practice and peer literature review.

6. Comparator

At the April 2015 meeting, MSAC agreed that the appropriate comparator was foot and ankle services provided by orthopaedic surgeons.

7. Comparative effectiveness

To address the issues and areas of uncertainty raised by MSAC in April 2015, the resubmission provided further information on the following issues.

Result and relevance of NRAS Review

The NRAS review was released on Friday 7 August 2015. The resubmission stated that the review's recommendations contained no reference to scope of practice.

MSAC agreed that the NRAS review did not provide any relevant information for the resubmissions assessment by MSAC.

Collaborative process, prioritisation and relevance to current practice of MBS item selection

The resubmission reaffirmed its previous list of requested MBS items. The resubmission stated that the list of 39 Medicare numbers is a discrete and prioritised list established in consultation with the Department of Health during the development stages of the Application. The list was developed from a process of rationalisation based upon robust research, which looked at the utilisation of MBS numbers for foot and ankle surgery by medical providers and incidence of surgical activity by podiatric surgeons in current practice.

Clarification of issues related to unmet need for podiatric surgeons' services

The resubmission provided further information on:

- patient need public consultation feedback, practitioner survey, public sector programs, Intergenerational Report, Access Economics Report
- professional support of need public consultation feedback and letters of support from professional bodies
- patient equity and choice
- broader health system issues.

Further information to address the evidence for podiatric surgeons' services non-inferiority to orthopaedic surgeons

The reapplication confirmed that no new evidence had become available since the previous application. However, references the possible relevance of the latest year's data from its ongoing audit, particularly to highlight that co-morbidities are now better captured, which might influence a casemix impression that podiatric surgeons more often handle the simple cases, leaving the orthopaedic surgeons to more often handle the cases complicated by co-morbidities.

Clarification of the scope of practice.

The College has a policy with respect to hospital credentialing which specifically addresses scope of practice according to standardised guidelines provided by the Australian Commission of Safety and Quality in Healthcare (Australian Commission of Safety and Quality in Health Care 2004, The Australasian College of Podiatric Surgeons 2015).

Published audits and peer review articles were presented to demonstrate that adverse outcomes experienced from the full scope of practice of ACPS fellows fit within and below national and international benchmarking (Bennett, Patterson, Butterworth, Tinley, Gilheany).

Four de-identified cases were provided to illustrate the podiatric surgeon as the primary care practitioner, directing the episode of care collaboratively within a multidisciplinary team.

Seven testimonials were provided highlighting the existing patient focused collaborative nature of the relationship between Fellows of the ACPS and medical practitioners in peri operative management.

MSAC had previously stated that it was beyond the remit of the committee to comment on scope of practice.

8. Key issues from ESC for MSAC

- Limited new information was provided in the resubmission.
- MSAC previously recommended that the applicant should delay its resubmission until the NRAS review findings regarding training and accreditation were made known. However, the NRAS review did not address the scope of practice.
- It is difficult to compare podiatric surgery and orthopaedic surgery as there is little high level evidence available.

9. Applicant's comments on MSAC's Public Summary Document

The conclusions of the MSAC are disappointing, particularly given the fact that numerous elements of the process have been misinterpreted and significant levels of robust evidence that supports the College's Application have been ignored. The numerous inconsistencies within the PSD suggests that the College's response to both the Medical Benefits Division's Overview of the Reapplication and the ESC Report have either been entirely misunderstood or simply ignored. At this point, however, the Draft PSD also includes some contradictions on behalf of MSAC's expectations, especially in relation to the collation of data comparisons between orthopaedic and podiatric surgeons which, given the potential role substitution, even MSAC does not believe will be created. The College has again identified a number of inconsistencies in the MSAC process in respect to its Application that raise significant concern about the management and consideration of documents, work undertaken in good faith regarding the rationalisation of the MBS items requested and the apparent discrimination against a surgical specialty who have significant and robust data supporting their clinical practice in favour of a specialty that has failed to create any equivalent data for comparison. The ACPS is concerned that, had appropriate consideration been given to the documentation and evidence provided by the College, a positive outcome would have resulted. In this respect, the Minister for Health and the Department of Health should consider and review how the Application was assessed and handled, especially in ensuring appropriate review and correction of errors of fact and misinterpretation.

10. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.