



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1344 – Assessment of Foot and Ankle Services by Podiatric Surgeons (foot and ankle conditions – various)

Applicant: Australasian College of Podiatric Surgeons

Date of MSAC consideration: MSAC 63rd Meeting, 1-2 April 2015

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

An assessment report requesting access by podiatric surgeons to a set of existing MBS-listed foot and ankle services was received from Australasian College of Podiatric Surgeons by the Department of Health in April 2014.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness of podiatric surgery vs orthopaedic surgery for 39 foot-related MBS items, MSAC did not support public funding for podiatric surgeons to access the items 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 PASC and ESC.

MSAC recommended reconsideration of the application when i) the National Registration and Accreditation Scheme review was complete, if relevant to the application and ii) the applicants 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.

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

MSAC noted that the October 2014 MSAC executive meeting recommended that the applicant defer its submission until the review of NRAS was complete. The applicant questioned the relevance of the NRAS review and due to lack of clarity, rejected the recommendation for deferral.

MSAC noted that the application was not a request for new MBS items, rather for access to existing items relating to foot and ankle surgery by podiatric surgeons. The proposed treatment algorithm placed podiatric surgeons as an alternative to orthopaedic surgeons for referral from general practitioners or medical specialists. This algorithm outlined identical treatment pathways for podiatric and orthopaedic surgeons. MSAC considered the argument for an unmet clinical need and agreed that there is increasing pressure on current orthopaedic services with surgical workforce shortages, population growth and ageing, and increasing prevalence of diabetes and obesity which this application sought to address by providing additional clinical resources in the form of podiatric surgeons.

MSAC noted, however, some concerns with this assessment of clinical need. Surgical waiting lists, while estimating how many people are waiting for surgery, do not provide accurate evidence of the extent to which podiatric surgeons would be able to reduce these lists. This is because there is a lack of data on how many people on waiting lists are waiting for foot and ankle surgeries. Given that many surgeries did not proceed, MSAC could not be sure that all of these could be considered essential.

MSAC considered the evidence presented to support the claim that treatment by a podiatric surgeon was non-inferior to treatment by an orthopaedic surgeon. While MSAC accepted that podiatric surgeons receive intensive training on the foot and ankle and agreed in principle that a podiatric surgeon would provide adequate care, the committee was concerned that the evidence presented in support of this claim was poor with data from the national audit of the Australian College of Podiatric Surgeons, 17 single-arm studies with low level data quality, and no direct randomised comparisons. MSAC concluded that the lower level evidence made the claim of non-inferiority uncertain, noting that this also does not show that services provided by podiatric surgeons are inferior to those provided by orthopaedic surgeons.

MSAC noted that it was beyond the remit of the committee to comment on scope of practice and could not provide the Minister with any assessment on competencies and standards of podiatric surgeons.

MSAC recommended that the applicant delay resubmission of an application for MBS items until the NRAS review findings regarding training and accreditation were made known.

MSAC noted some consumer support for the application as a means to provide greater access to foot and ankle services.

MSAC noted that the financial or budgetary implications of podiatric surgeon access to MBS items were uncertain. These depended on the numbers of podiatric and orthopaedic surgeons available and whether the model was based on a substitution of services normally delivered by orthopaedic surgeons, or additional services provided. MSAC also noted that MBS funding could result in increased numbers of trainee podiatric surgeons.

MSAC noted the application's description of a model where podiatric surgeons manage a whole episode of care. Under the MBS fee-for-service model, this description could entail management transfer to other practitioners under certain circumstances.

MSAC recommended that the applicant work with the Department of Health to develop a subset of the 39 listed MBS items based on the services currently being provided by podiatric surgeons and areas of demonstrated unmet need.

4. Background

Foot and ankle services provided by podiatric surgeons have not been considered by MSAC previously.

5. Prerequisites to implementation of any funding advice

The application indicated that the MBS items would be available to podiatric surgeons only if patients were referred directly from a general practitioner, physician or specialist.

Currently, podiatric surgeons do not have admitting rights in any public hospital in Australia and procedures are therefore carried out in private hospitals and day surgery sites.

As podiatric surgery and consultations rendered by podiatric surgeons are not currently covered by MBS items, patients access these services via private health insurance or self-funded means.

The proposal posits podiatric surgeon services that are unrestricted to a particular setting. This would require podiatric surgeons to increasingly work in multidisciplinary teams, in the same manner of orthopaedic surgeons currently operating in public settings.

Podiatric surgeons are podiatrists who have undertaken a national board-approved program of accredited surgical training before becoming eligible for specialist recognition as a podiatric surgeon. Currently, there are 26 accredited and registered podiatric surgeons in Australia.

The Podiatry Board of Australia, established under the National Registration and Accreditation Scheme administered by the Australian Health Practitioner Regulation Agency (AHPRA), registers podiatrists and podiatric surgeons. Podiatric surgeons are not registered by the Medical Board of Australia. Podiatric surgeons have only limited access to Medicare and cannot claim rebates for surgical services.

6. Proposal for public funding

Podiatric surgeons are podiatrists who have completed intensive postgraduate training in podiatric medicine and surgery. Podiatric surgeons are trained with a focus on the diagnosis, assessment, treatment and management of foot and ankle conditions. Currently podiatric surgeons provide foot and ankle surgical procedures through private practice—private hospitals or private out-of-hospital clinics.

The application requested podiatric surgeons' access to a set of 39 surgical treatments, services and consultations for conditions of the foot or ankle, already provided on the MBS. Other medical practitioners such as general practitioners (GPs), orthopaedic and plastic surgeons currently access these MBS items.

The application nominated eight clinical conditions, all within the scope and training credentials of the podiatric surgeon. They included:

- hallux abducto valgus;
- hammer and claw toes;
- hind foot/ankle pathology;
- ingrown toenails;
- hallux rigidus;
- heel pain;

- nerve impingement; and
- tumour (benign).

The application also sought MBS access to co-administered services that are routinely used in conjunction with the identified procedures such as diagnostic imaging, pathology, and anaesthesia. The application also requested referral rights for podiatric surgeons, equivalent to orthopaedic surgeons’.

7. Summary of Public Consultation Feedback/Consumer Issues

No specific consumer impact statement was provided in the assessment. Several consumer responses were received during the public consultation period, which generally supported the proposal seeing this as a means of providing greater access to foot and ankle surgery services, particularly for the increasing ageing population.

Two of the five responses from professional organisations considered that the evaluation of podiatric surgeons’ surgical training standards and competencies was not the remit of MSAC.

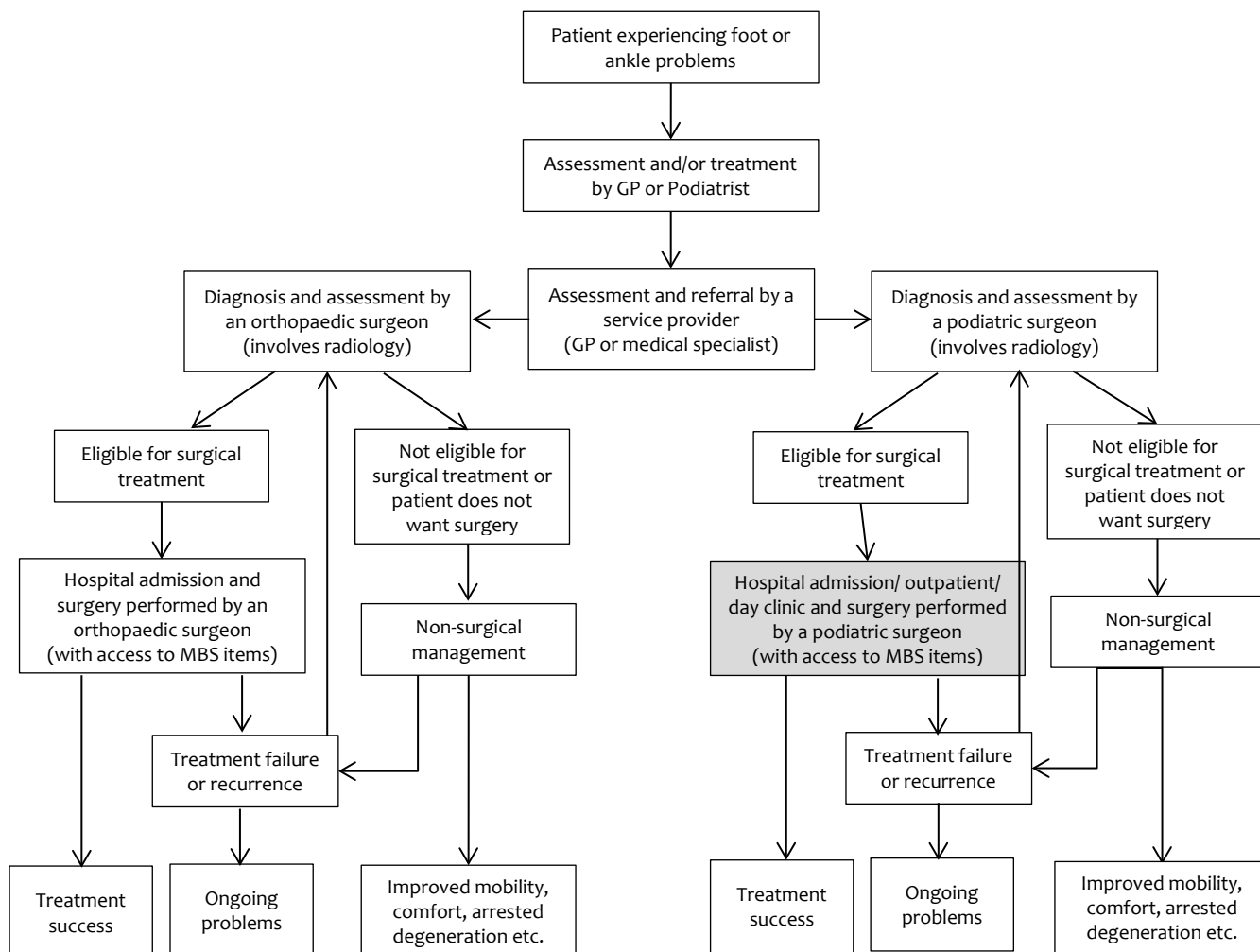
8. Proposed intervention’s place in clinical management

Therapeutic foot and ankle surgical procedures, services and medical consultations provided by podiatric surgeons are expected to offer an alternative provider option. Foot and ankle MBS services are currently primarily performed by general practitioners and orthopaedic surgeons. The application considers this potential re-organisation of the workforce critical, particularly against a backdrop of:

- Extensive public hospital waiting lists for orthopaedic surgeons above national average for surgery. Long waiting periods for surgery increases the time individuals spend with pain, suffering and reduced quality-of-life. Early foot care in diabetes can prevent more surgery like amputations later;
- Workforce shortage of surgeons, including orthopaedic (Royal Australian College of Surgeons 2011);
- Population growth coupled with an ageing Australian population, likely to significantly increase the demand for health services related to foot and ankle pathology (Access Economics 2008). Foot conditions worsen over time and may be associated with chronic conditions such as diabetes, whose prevalence has more than doubled in the last two decades (AusDiab 2012);
- The extent of unmet clinical need as result of the current model of care where the efficiency and continuity of patient care could be improved; and
- Rising prevalence of foot problems, which are reported by nearly one in five people in the general population. Prevalence is highest among females: those aged over 50 years; those classified as obese; and those who report knee, hip or back pain (AIHW 2009).

The proposed clinical management algorithm for the intended use of foot and ankle surgery is shown in Figure 1.

Figure 1: Proposed clinical management algorithm



Source: Figure A.3, p34 of the application
 GP = general practitioner

It should be noted that, while outpatient and day clinic settings are listed in the algorithm, most of the MBS items are proposed for admitted (in-hospital) patients.

9. Comparator

MSAC agreed that the appropriate comparator was foot and ankle services provided by orthopaedic surgeons. The main arguments provided by the application were that podiatric surgeons align closest to orthopaedic surgeons in terms of their: skillsets; the conditions treated; the model of care ('whole of episode'); patient assessment with diagnostic testing; procedure variety and post-operative care. The main differences between the two specialities are listed in Table 1.

Table 1: Key differences among Australian podiatric and orthopaedic surgeons (current)

-	Podiatric surgeon	Orthopaedic surgeon
Referred by	Podiatrists 59% , GPs 35%, specialist 6% - referral not required	GPs, specialists (unknown %) - required for the consultation to be eligible for MBS benefits
Operating settings	Private hospital 80%, private clinic 20%	Private hospital, private clinic, public hospital
Number of surgeons	26 accredited, 19 actively practicing	1211 registered, of these 99 specialize in ankle/foot
Patient types	Fewer trauma patients (elective patients) Greater number of patients >55 years Greater number of patients for 1 st MJP	More trauma patients (public hospitals) Greater number of patients < 14 years, 35-44 years Greater number of patients for ankle surgeries and amputations
Number of patients	Each surgeon: weighted average = 46 per month or 553 per year	Each surgeon: unknown
Number of key foot/ ankle procedures ¹	1062 in 2013 (private setting only)	32,145 in 2013 (private setting only)
Referrals to	Cannot refer directly to other medical specialties	Can refer directly to other medical specialties
Pathology testing and diagnostic imaging services	Full requesting rights but only a limited number of diagnostic imaging services are eligible for MBS benefit. Remaining incur private patient costs. Pathology testing is not eligible for MBS benefits and incurs patient costs.	All pathology and diagnostic imaging requests are eligible for MBS benefits.
Medication prescribing rights	Limited prescribing rights. Prescriptions are not eligible for subsidy through the PBS (private prescriptions only).	Full prescribing rights. Prescriptions eligible for subsidy through the PBS.
Working with multi-disciplinary teams	Work with anaesthetists and theatre staff in hospitals/surgical setting. Refers to other specialists as required via GPs or the patient's referring specialist. Works with the medical team.	Works with anaesthetists and theatre staff in hospitals/surgical setting. Refers directly to other specialists as required. Works with the medical team.

Source: Figures B1, B2 pp40-41, Table A.6 p36 of application, ACPs survey Section D worksheet of the submission

GP = general practitioner; MJP = metatarsophalangeal joint; PBS = Pharmaceutical Benefits Schedule

1. Six procedural groups for meaningful comparison: 1st metatarsophalangeal joint, lesser toe, neuroma, rear foot & heel, ankle, amputations.

10. Comparative safety

The application stated that the issue being addressed in this assessment was not one of efficacy, safety and cost-effectiveness of a new medical/surgical procedure or intervention; rather, the issue was whether MSAC considered the outcomes of surgeries and consultations requested by podiatric surgeons to be non-inferior when compared to orthopaedic surgeons performing the same procedures.

The application concluded that surgery provided by podiatric surgeons has a safety profile comparable to that for orthopaedic surgeons.

The critique noted that the claim that podiatric surgeons and orthopaedic surgeons had similar safety outcomes was not well supported by the evidence presented. For orthopaedic surgeons, the assessment of infection and complication rates was based on only one small study (80 procedures), and the generalisability of the findings was limited.

For podiatric surgeons, five studies and the 2013 Australasian College of Podiatric Surgeons Audit were presented that examined infection and complication rates for podiatric surgeons.

Overall, the studies presented indicated low rates of infections, general complications and venous thromboembolism for both podiatric and orthopaedic surgeons.

11. Comparative effectiveness

The application provided data from the 2013 audit by the Australasian College of Podiatric Surgeons (ACPS). To determine the scope of practice across the two specialities, the audit data was compared with MBS online item reports. The limitations of the MBS data included: the scope of collection; the inability to determine patient numbers; the underestimation of foot and ankle procedures when generic codes are used and the health providers could include orthopaedic, general or plastic surgeons or GPs (the latter often perform toenail surgery). The audit produced data on six procedural groups provided by both podiatric and orthopaedic surgeons; 1062 procedures by podiatric surgeons compared with 32,145 procedures by MBS providers.

The application stated that podiatric surgeons treat the same types of patients with the same types of procedures, complexity and severity as orthopaedic surgeons.

MSAC noted that it was beyond the remit of the committee to comment on scope of practice.

Table 2 below provides a summary of the training requirements across the two specialities.

Table 2: Summary of key training requirements of podiatric and orthopaedic surgeons

Domain	Podiatric surgeons	Orthopaedic surgeons
Undergraduate training	Four year undergraduate Bachelor of Podiatry	Four to six year medical degree via either an undergraduate or graduate entry pathway
Post graduate training	3 years full-time equivalent via ACPS Training Program or Doctor of Podiatric Medicine at UWA. Emergency and critical care courses Regional and specialist medical and surgical rotations International preceptorships	5 years SET in orthopaedic surgery Emergency and critical care courses Medical and surgical rotations
Eligibility criteria	<u>ACPS Training Program</u> Hold general registration with the Podiatry Board of Australia. Be a citizen or permanent resident of Australia or NZ Have a minimum of two years clinical experience working as a podiatrist. Fulfil minimum educational requirements including: Endorsement for Scheduled Medicines under Australian registration. Completion of an approved Master's degree within a discipline that has relevance to the speciality field of podiatric surgery. Hold Affiliate membership of the ACPS. Be eligible for attainment of appropriate professional indemnity insurance. <u>Doctor of Clinical Podiatry</u> A Bachelor of Podiatric Medicine from UWA or a recognised equivalent; and At least one year's relevant professional experience.	Permanent residency or citizenship status of Australia or New Zealand; General (unconditional) registration in Australia or general scope or restricted general scope registration in the relevant specialty in New Zealand. Successful completion of the RACS Hand Hygiene Learning Module from Hand Hygiene Australia Completion of an eight week postgraduate term in an Emergency Unit; and Completion of at least 26 working weeks of orthopaedic surgical experience within the last two years, at least three years or higher following completion of primary medical degree Ability to demonstrate satisfaction of the competency-based requirements for entry into the SET program.
Selection criteria	<u>ACPS Training Program</u> ACPS Entrance examination. Psychometric and motor skills testing. Interview. <u>Doctor of Clinical Podiatry</u> -Available from UWA	Assessment via curriculum vitae IDR reports (five surgeons and two non-surgeons)
Minimum clinical hours/case	Regional rotation: 240 hours Medical and surgical specialty: 320 hours	Not available. <i>This omission is important since it is unclear what clinical experience is minimally required.</i>

Domain	Podiatric surgeons	Orthopaedic surgeons
numbers (foot/ ankle specific)	Minimum cases numbers: 1,970	
Registration details	Specialist registration acknowledged as a podiatric surgeon	Specialist registration acknowledged as an orthopaedic surgeon.

Source: Table B.8, p57 of the application

ACPS = Australasian College of Podiatric Surgeons; IDR = integrated data repository; SET = Surgical and Education Training; RACS = Royal Australian College of Surgeons; UWA = University of Western Australia

A summary of the key features of the studies included in the assessment as supporting evidence is provided in Table 3.

Table 3: Summary of key features of all included studies

Trial	Total N	Design/ duration	Risk of bias	Patient population	Outcome(s)
Podiatric surgeon studies	-	-	-	-	-
Dux 2013	59	Single arm, 6-12 months	High	Foot surgery	FFI-R
Armanasco 2012	116	Case control, < 20 months	High	Foot surgery	PAT SAT
Rusmir 2011	111	Single arm, 6 years	High	Post-operative	Infections
Spruce 2011	179	Single arm, 1045 days	High	Foot surgery	FHSQ, PATSAT
Butterworth 2010	1,339	Single arm, 12 months	High	Post-operative	Infections
Maher 2009	917	Single arm, 4 years	High	Foot surgery	FHSQ, PAT SAT, Infections, Complications, VTE
Kilmartin 2002 ^a	2,335	Single arm, 4 years	High	Foot surgery	PAT SAT, Complications, VTE
Kilmartin 2002 ^b	244	Single arm,	High	Post-operative	Infections, Complications
Bennett 2001	140	Single arm, 6 months	High	Foot surgery	FHSQ, PATSAT, SF-36
Sticha 1998	100	Single arm,	High	Post-operative	Infections
Orthopaedic surgeon studies	-	-	-	-	-
Dawson 2012	491	Single arm, 9 months	High	Foot and ankle surgery	SF-36
Canesco 2012	19	Single arm, 16 months	High	Foot and ankle post-operative	SF-36
Jameson 2011	88,241	Single arm, 90 days	High	Post-operative	VTE
Murray 2010	40	Single arm, 3 months	High	Bilateral foot surgery	PAT SAT, AOFAS, Infections
Saro 2007	94	Single arm, 12 months	High	Foot surgery	AOFAS, SF-36

Source: constructed during evaluation

AOFAS = American Orthopaedic Foot and Ankle Society; FFI-R = revised foot function index; FHSQ = foot health and safety questionnaire; PAT SAT = patient satisfaction; SF-36 = Short form 36 health survey; VTE = venous thromboembolism

The critique noted that no direct comparisons could be made across the studies because, with one exception (Armanasco 2012), no study included patients in the same setting treated by either podiatric or orthopaedic surgeons. Comparison across single-arm studies was difficult because few outcomes were common across the studies. In the wider literature on ankle and foot clinical research, there was also a lack of standardised outcomes and no single outcome measure was preferred.

For comparative purposes, the results for health-related quality-of-life using the SF-36 and some safety outcomes were possible but limited (Table 4). The SF-36 subscales were not combined into the Physical and Mental Component Scores in the studies, and assessing minimal important differences was not possible.

Table 4: Results of comparative analysis: SF-36 health survey scores^{1,2}

Domains: Studies	Podiatric Surgeons			Orthopaedic Surgeons		
	Pre-op	Post-op	Mean change	Pre-op	Post-op	Mean change
Validity	-	-	-	-	-	-
Bennett 2001 ^a	70.0	72.0	2.0	-	-	-
Dawson 2012	-	-	-	NR	NR	1.6
Saro 2007	-	-	-	62.0	71.0	9.0
Canseco 2012	-	-	-	67.8	67.8	0.0
Physical functioning	-	-	-	-	-	-
Bennett 2001 ^a	80.0	92.0	12.0	-	-	-
Dawson 2012	-	-	-	NR	NR	6.7
Saro 2007	-	-	-	82.8	86.4	3.6
Canseco 2012	-	-	-	77.8	93.5	15.7 [*]
General health	-	-	-	-	-	-
Bennett 2001 ^a	74.0	74.0	0.0	-	-	-
Dawson 2012	-	-	-	NR	NR	-1.6
Saro 2007	-	-	-	76.6	78.8	2.2
Canseco 2012	-	-	-	79.9	83.3	3.4
Social role functioning	-	-	-	-	-	-
Bennett 2001 ^a	87.0	88.0	1.0	-	-	-
Dawson 2012	-	-	-	NR	NR	5.8
Saro 2007	-	-	-	83.4	89.1	5.7
Canseco 2012	-	-	-	88.3	90.2	1.9

Sources: Constructed during evaluation from Bennett *et al.* 2001, Dawson *et al.* 2012, Saro *et al.* 2007, Canseco *et al.* 2013.

NR = not reported, op = operative

1. Score range 0-100 - higher scores indicate higher quality of life.
2. Bennet *et al.* 2001 did not present all SF-36 domain scores.

The application concluded the efficacy of procedures performed by podiatric surgeons to be at least non-inferior to that of procedures performed by orthopaedic surgeons. The application also concluded that podiatric surgeons delivered superior patient relevant outcomes, such as patient satisfaction (Armanasco 2012), compared to orthopaedic surgeons.

The critique noted, however, that these claims were not supported by the clinical evidence presented. The applicant disagrees with this assessment.

Table 5 summarises the outcomes for infection, complication and venous thromboembolism rates.

Table 5: Summary of infection, complication and venous thromboembolism rates

-	-	Infection rate		-	Complication rate		-	VTE rate	
		n	%		n	%		n	%
-	No. procedures								
Podiatric surgeon	-	-	-	-	-	-	-	-	-
Maher 2009	2772	18	1.96	184	4.8 ^a	0	0		
Kilmartin 2002a	2335	32	1.3	247	10.5	9	0.3		
Butterworth 2010	2387	74	3.1	-	-	-	-		
Rusmir 2011	111	21	18.9	-	-	-	-		
Kilmartin 2002b	197	9	5	23	13	-	-		
Sticha 1998	100	1	1	-	-	-	-		
Hugar 1990 [*]	148	2	1.35	-	-	-	-		
Orthopaedic surgeon									
Murray 2010	80	1	1.25	5	6.25	-	-		
Jameson 2011	88241	-	-	-	-	58	0.1		

VTE = venous thromboembolism

The studies found low rates of infections, general complications and venous thromboembolism for both podiatric surgeons and orthopaedic surgeons. The application concluded that podiatric surgery had a safety profile comparable to that for orthopaedic surgeons.

Premodelling studies:

To address applicability issues, the application provided:

1. comparability of surgical techniques performed by each discipline with consideration to complexity of case and disease severity (casemix);
2. comparability of orthopaedic versus podiatric surgeon surgical procedure setting, and
3. the applicability of international training in Australia.

12. Economic evaluation

In place of an economic evaluation, the submission provided a financial analysis of podiatric surgeons' proposed access to the specified MBS items.

13. Financial/budgetary impacts

Financial estimates were derived from the Australasian College of Podiatric Surgeons national audits 2012 and 2013, a survey of podiatric surgeons registered with the Australasian College of Podiatric Surgeons, and expert opinion.

Table 6 provides the forecast for net financial cost to the MBS; Table 7 provides the associated sensitivity analyses.

Table 6: Total net cost to the MBS

Cost per Year	Year 1	Year 2	Year 3	Year 4	Year 5
Cost of MBS items for podiatric surgeons (net)	\$1,499,961	\$1,535,958	\$1,682,240	\$1,971,377	\$2,143,756
Cost of co-administered services	\$288,861	\$317,772	\$348,018	\$379,662	\$414,560
Total cost podiatric and co-admin services	\$1,788,822	\$1,853,730	\$2,030,258	\$2,351,039	\$2,558,316
Cost off-sets from GP visits avoided	-\$59,514	-\$65,465	-\$71,700	-\$78,218	-\$85,329
Net cost to MBS	\$1,729,308	\$1,788,264	\$1,958,557	\$2,272,821	\$2,472,987

Table 7: Sensitivity analysis of the estimated net cost to the MBS

	Year 1	Year 2	Year 3	Year 4	Year 5
Net cost to MBS (base case)	\$1,729,308	\$1,788,264	\$1,958,557	\$2,272,821	\$2,472,987
1. 100% substitution from orthopaedic surgeons	\$229,347	\$252,307	\$276,318	\$301,443	\$329,231
2. Restrict patient numbers for referrals only	\$673,903	\$694,564	\$760,705	\$885,708	\$963,580
3. Two way sensitivity combining 1 and 2 above	\$58,919	\$64,821	\$70,987	\$77,443	\$84,641
4. Double the number of surgery items	\$3,518,130	\$3,641,994	\$3,988,815	\$4,623,860	\$5,031,303
5. Double the number of co-administered services	\$2,018,169	\$2,106,037	\$2,306,575	\$2,652,483	\$2,887,548
6. Two-way sensitivity combining 4 and 5 above	\$4,095,851	\$4,277,539	\$4,684,851	\$5,383,184	\$5,860,424
7. Higher anaesthetist cost (average time at 75 th percentiles 2012 2013= 2:36 hours – MBS 23112 \$237.60)	\$1,765,089	\$1,827,623	\$2,001,665	\$2,319,847	\$2,524,288
8. Higher patient load 60/month or 720 per year (Base case 46/month)	\$1,937,798	\$1,983,289	\$2,172,156	\$2,546,836	\$2,770,829
9. Higher number of accredited podiatric surgeons (4 in 2018, 7 in 2019)	\$1,729,308	\$1,788,264	\$1,958,557	\$2,540,291	\$3,090,039
10. Two-way sensitivity analysis combining 8 and 9 above	\$1,937,798	\$1,983,289	\$2,172,156	\$2,848,558	\$3,466,810

The application estimated that the net cost to the MBS would be at most about \$6 million in year 5. The sensitivity analysis showed that:

- The net cost to the MBS was significantly reduced when patient numbers, number of surgeries was reduced or full substitution occurred.

- The net cost to the MBS was significantly increased when allowing for double the number of surgeries or co-administered items.
- The financial estimates were dependent on the number of accredited podiatric surgeons over time and, in turn, the number of patients they would treat. The estimates were sensitive to these two factors as shown in row 10 of Table 7.

The critique noted that the estimated number of MBS services was 18,862 in year 1 rising to 26,714 in year 5. This included all the surgical and co-administered services requested in the application and related to 1,606 surgical procedures in year 1 and 2,303 in year 5. The number of patients and surgical services was entirely dependent on the existing pool and expected number of newly accredited podiatric surgeons during these years and their patient caseload. There would be potential for the net cost per year to the MBS, if podiatric surgeon services were to be MBS funded, to be greater than estimated in the application.

The applicant preMSAC response noted that the financial and other forecasts include future podiatric surgeons currently training in Australia.

14. Key issues from ESC for MSAC

Evidence

ESC considered that the evidence presented in support of the application was insufficient to support the applicant's claim that podiatric surgeons were non-inferior to orthopaedic surgeons, noting that this also does not show that services provided by podiatric surgeons are inferior to those provided by orthopaedic surgeons.

Evidence was drawn from 17 single-arm studies and the primary data in support of the application was drawn from the Australian College of Podiatric Surgeons 2013 national audit.

Unmet need

Demand for foot surgery is increasing due to the ageing Australian population, the rising diabetic complications and the rising waiting lists for orthopaedic surgery. However, as the waiting lists for orthopaedic surgery cannot be separated out, there are no data on how many people on the waiting lists are waiting for foot and ankle surgeries.

ESC was uncertain whether there is an unmet need in non-complex cases, the impact of an increase in podiatric surgical services, or whether there would be an increase in some procedures.

Financial implications

ESC was concerned that the patient numbers in the application may have been underestimated.

The financial impact was assessed to be modest (\$6 million maximum in 5 years), based on a conservative approach which counted additional services rather than substitution of services. A key driver in the estimates was the potential growth in accredited podiatric surgeons. However, there were still a number of unknown factors around rates of adverse events, follow up care, or whether podiatric surgeons potentially performed more operations than orthopaedic surgeons.

There was a lack of consideration of the additional referrals from GPs or medical specialist that would be needed to replace the referrals currently provided by general podiatrists. Also,

as podiatric surgery is conducted in the private setting, if listed, this would potentially impact on private health insurance as insurers would be required to pay at least the 25% difference between the MBS fee and the 75% benefit, however, the level of this impact is unclear but likely to be minimal.

Training and accreditation

The comparator selected by the applicant is orthopaedic surgeons undertaking the procedures. While this comparator is reasonable it raises some concerns with regard to training and accreditation. The application identifies a difference in duration and type of training for podiatric and orthopaedic surgeons (Podiatric: 4 years Bachelor of Podiatry + 3 years post graduate training, and Orthopaedic: 4-6 years medical degree + 5 years orthopaedic training).

The authority for assessing podiatric surgeons training currently resides with the Australian and New Zealand Podiatry Accreditation Council in accordance with the accreditation standards approved by the Podiatry Board of Australia under the *Health Practitioner Regulation National Law 2009*. Those standards are being considered as part of an independent review of the National Registration and Accreditation Scheme (NRAS). ESC queried whether the NRAS review would be useful for consideration of this application or whether it would just be used for quality assurance.

ESC considered that recognition of training and accreditation is an industrial issue that MSAC should not need to consider in its evaluation of the proposed MBS services.

15. Other significant factors

Nil.

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

The conclusions of the MSAC are disappointing. The applicant considers numerous elements of the process have been misinterpreted and significant levels of robust evidence that supports the College's Application have been overlooked. At this point, however, the PSD does provide some basis for discussion to move forward towards a positive MSAC recommendation in future. In respect to this application, the College has clearly identified inconsistencies in the inappropriateness of RCTs for this application, in regards to the item numbers applied for and the significant level of robust evidence that exists demonstrating the safety of podiatric surgery. Even allowing for these issues however, the PSD acknowledges many positives in respect to podiatric surgeons such as the acceptance of orthopaedic surgeons as the comparator and acknowledgment of the detailed and accredited level of training of podiatric surgeons. The ACPS is concerned however that, greater consideration should have been given to the College's pre-MSAC comments (http://acps.edu.au/pub_govsubmissions.php).

17. Further information on MSAC

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