



Australian Government

Medical Services Advisory Committee

## Public Summary Document

### ***Application No. 1344.2 – Assessment of foot and ankle services by podiatric surgeons (Resubmission)***

**Applicant:** Australian College of Podiatric Surgeons

**Date of MSAC consideration:** MSAC 78<sup>th</sup> Meeting, 3 April 2020

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

#### **1. Purpose of application**

A resubmission requesting access for podiatric surgeons to a limited number of Medicare Benefits Schedule (MBS) items for surgery of the foot and ankle was received from the Australian College of Podiatric Surgeons (ACPS) by the Department of Health.

#### **2. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support podiatric surgeons having access to the requested MBS items for surgery of the foot and ankle. MSAC noted that the applicant had reduced the set of requested MBS items to 23 (from 39) surgical items, plus five (5) general items. MSAC considered, however, that there remains a lack of directly comparable evidence for safety and effectiveness, albeit primarily because of the paucity of high-quality contemporary evidence for the safety and effectiveness of the same services delivered by orthopaedic surgeons. MSAC also considered the evidence for unmet need remains unclear.

MSAC advised that in the absence of a significant new body of evidence becoming available on the safety and effectiveness of the specified services when delivered by orthopaedic surgeons, it would be unlikely that a further comparative Health Technology Assessment of the sort MSAC typically relies upon would be sufficiently informative for MSAC to provide different advice on this matter.

Consistent with its previous advice for applications 1344 and 1344.1, MSAC noted that evaluating issues relating to scope of practice and accreditation are outside its remit and remain matters for the Australian Health Practitioner Regulation Agency (AHPRA).

## Consumer summary

The Australian College of Podiatric Surgeons requested that podiatric surgeons be able to access 28 Medicare Benefits Schedule (MBS) items for surgery of the foot and ankle. These items relate to treating bunions, hammer and claw toes, problems with the back of the foot, ingrown toenails, loss of flexibility in the big toe, arthritis, nerve problems in the foot and ankle, and noncancerous tumours.

Unlike orthopaedic surgeons, who also do foot and ankle surgery, podiatric surgeons usually work in private practice and are not able to claim MBS items. This can mean that patients have high out-of-pocket costs for podiatric surgery.

This was the third time that the Medical Services Advisory Committee (MSAC) had considered this application. The applicant had provided some extra data at MSAC's request, and reduced the number of MBS items requested. MSAC also noted the extensive input received from consumers for this application. MSAC acknowledged that some consumers prefer services delivered by podiatric surgeons and incur out-of-pocket costs as a result.

After carefully assessing all of the available data, MSAC still could not be satisfied that podiatric surgeons could deliver the same or better clinical outcomes than orthopaedic surgeons. However, MSAC noted that this did not necessarily mean that services provided by podiatric surgeons are not as good as those provided by orthopaedic surgeons.

MSAC was also not convinced that demand for these services was increasing more than demand for all MBS services, and it was not clear that allowing podiatric surgeons to access the MBS would reduce patient waiting times or out-of-pocket costs.

### **MSAC's advice to the Commonwealth Minister of Health**

MSAC did not support that podiatric surgeons have access to the requested MBS items. This was because there was not enough evidence to show that podiatric surgeons could deliver the same or better clinical outcomes than orthopaedic surgeons.

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

MSAC noted the substantial number of responses to consultation (119 responses: 10 groups, 43 podiatrists, 11 podiatric surgeons, 1 orthopaedic surgeon, 3 GPs, 13 other practitioners, 49 consumers/caregivers). Common themes in the consultation feedback were that MBS listing would reduce out-of-pocket costs, reduce waiting time for surgery, improve access and equity of choice, and improve patient quality of life. However, MSAC noted that patients are able to access these services through existing orthopaedic surgeons who specialise in foot and ankle surgery, and that it remains unclear whether access to the MBS for podiatric surgeons would reduce out-of-pocket costs or improve access.

MSAC also noted some consultation submissions questioned the training, credentialing and scope of practice of podiatric surgeons. As with previous submissions, MSAC noted these issues fall outside its remit and instead belong to AHPRA.

MSAC recalled it had requested five key issues be addressed by this resubmission:

- Justification for a discrete set of MBS items relevant to current scope of practice for podiatric surgeons

- Evidence of unmet need for podiatric surgeons' services
- Evidence of non-inferiority of outcomes between services delivered by podiatric surgeons compared to the same services delivered by orthopaedic surgeons
- Impacts on MBS expenditure of extending access to podiatric surgeons for those items for which there is demonstrated non-inferiority in outcomes
- Assurance about the complete package of care delivered to patients, including the ability of podiatric surgeons to work in multidisciplinary teams.

Regarding the discrete set of MBS items, MSAC noted the applicant had reduced the request to 23 (from 39) existing surgical items plus 5 general items. The new proposed population comprises eight clinical groupings. Evidence to support this request was primarily data from the ACPS registry, which ESC considered was the best available evidence of current Australian practice for podiatric surgeons. The applicant estimated that 66% of podiatric surgery procedures would be covered by the 23 requested MBS items based on mapping of International Classification of Diseases-version 10 (ICD-10) codes for procedures at the state level to MBS items at the national level. MSAC noted the podiatric surgeons request was for access to the same MBS items that are used by orthopaedic surgeons, rather than for a discrete set of items. MSAC noted the issue of whether two groups of practitioners should have access to the same MBS items, or should have separate items, was primarily a policy and administrative issue for the Department.

Regarding evidence of unmet need, MSAC noted the data on hospital wait times for elective orthopaedic surgery of the foot and ankle, and the applicant's pre-MSAC response describing how these wait times relate to the requested clinical groupings. However, MSAC considered that the applicant's claim of increasing demand for foot and ankle surgeries was not well substantiated, as the increase in demand is in line with overall increases in demand for MBS services.

Regarding evidence of non-inferiority, MSAC noted and agreed with the ESC comments with respect to the lack of directly comparable evidence for safety and effectiveness.

MSAC noted the applicant's pre-MSAC response reasonably asserted that the applicant's analysis contained the best available data sources, including those recommended for use by the MSAC, to demonstrate the safety and efficacy of the work undertaken by podiatric surgeons. MSAC noted the resubmission's key evidence was an indirect comparison of outcomes for patients treated by podiatric surgeons from the ACPS registry (n=8,142) over the past 5 years with administrative data from patients treated by orthopaedic surgeons available from South Australia Health (n=9,337) and Tasmania Health (n=2,851). MSAC agreed with the applicant that these datasets provide the best available Australian evidence.

Overall however, for the reasons set out by the ESC, MSAC was not able to satisfy itself that comparable clinical outcomes will be achieved when the specified services are delivered by podiatric surgeons compared with orthopaedic surgeons. MSAC noted this was primarily because of the paucity of high-quality contemporary evidence for the safety and effectiveness of the services delivered by orthopaedic surgeons (relative to the evidence that is available for podiatric surgeons from the ACPS registry) and acknowledged that although non-inferiority could not be established, this did not necessarily mean that services provided by podiatric surgeons are inferior to those provided by orthopaedic surgeons.

Regarding the impacts on MBS expenditure, MSAC considered that, because non-inferiority could not be established, the impact on the MBS remains uncertain.

Regarding the complete package of care provided by podiatric surgeons, MSAC remained concerned about provision of holistic patient care, liaison with other health professionals and multidisciplinary team care, however noted that this is due to lack of opportunities for podiatric surgeons to work in multidisciplinary teams in Australia (for example in public hospital multidisciplinary teams). MSAC noted there was limited discussion in the application of podiatric surgeons' ability to provide an equivalent package of care to an orthopaedic surgeon, including pre-operative and post-operative care, and management of complications. Evidence presented from overseas was not considered to be applicable to the Australian context.

MSAC advised that in the absence of a significant new body of evidence becoming available on the safety and effectiveness of the specified services when delivered by orthopaedic surgeons, it would be unlikely that a further comparative Health Technology Assessment of the sort MSAC typically relies upon would be sufficiently informative for MSAC to provide different advice on this matter.

#### 4. Background

This is the second resubmission (applicant-developed assessment report; ADAR) of Application 1344. In the previous resubmission (Application 1344.1) the MSAC did not support public funding due to a lack of evidence for comparative safety and effectiveness in relation to comparable services, and the clinical need remained uncertain ([MSAC - 1344.1 - Assessment of foot and ankle services by podiatric surgeons \(Resubmission\)](#), March 2016, p1).

The Commentary provided a detailed summary of previous MSAC issues from the previous resubmission (Application 1344.1) and how the ADAR has addressed them in current resubmission (Application 1344.2) [Table 1].

**Table 1 Summary of MSAC recommendations from Application 1344.1 and Critique's summary of the approach used in the current resubmission**

MSAC issues/recommendations based on MSAC 1344.1	How these recommendations have been addressed in 1344.2
Clinical need remained uncertain [PSD, p1]	The applicant provided an analysis of AIHW data showing long wait times for public hospital elective orthopaedic surgery, and long-term growth in demand for MBS funded foot and ankle surgery and elective orthopaedic surgeries, GP encounters related to plantar fasciitis, MBS-funded podiatric services available to people with chronic medical conditions and the prevalence of foot pain.
Consider a discrete set of items relevant to their scope of current practice [PSD, p2]	The applicant has almost halved its number of requested surgical MBS items (23 existing surgical items and 5 general items, from 39) to ensure each item is linked to evidence of Australian and international activity with non-inferior or superior outcomes, and specified services that cover the range and complexity of podiatric surgeons' established scope of practice in Australia and internationally.

<b>MSAC issues/recommendations based on MSAC 1344.1</b>	<b>How these recommendations have been addressed in 1344.2</b>
<p>Applicant needs to provide direct comparative evidence demonstrating the non-inferiority of podiatric surgeons to orthopaedic surgeons, both with regards to safety and efficacy [PSD, p3].</p> <p>Applicant could consider international evidence 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 [PSD, p3].</p>	<p>The applicant has provided analysis of safety and effectiveness outcomes utilising ACPS registry data and compared this to orthopaedic surgery data sourced from Tasmanian and South Australian Department of Health data sets.</p> <p>The applicant has included published and unpublished data about safety and effectiveness outcomes for podiatric surgery in both the UK and United States (US), two comparable jurisdictions to Australia in terms of podiatric surgery training and practice.</p>
<p>Availability of audit data comparing podiatric surgeons and medically qualified surgeons working in the same setting in other countries [PSD, p2]</p>	<p>The applicant has included both published and unpublished studies from the UK and US (Joyce et al. 2019, Cichero et al. 2019, Chan et al. 2018) to address this issue. Of these studies, only Chan et al (2018) provides a direct comparison of outcomes between podiatric and orthopaedic surgeons.</p>
<p>Lack of long-term follow-up in the data in case series evidence [PSD, p3]</p>	<p>There is a lack of published studies incorporating long term follow-up of patient outcomes.</p>
<p>MSAC's uncertainty relating to podiatric surgeons' case mix, and the possibility that in private practice, they are exposed only to selected uncomplicated cases that are more likely to have better outcomes, [compared with orthopaedic surgeons' case mix]. [PSD, p2]</p>	<p>The aforementioned analysis of ACPS Registry data compared to health data from Tasmania and South Australia has been used to indirectly address the issue of comparability of scope of practice between the two groups of surgeons. Further to this, three further references (Amanasco et al. 2012, Bennett 2007, and Laxton 1995) have been included to demonstrate comparability of types of surgery performed between the groups. The related issue of differences in practice setting, and differences in complexity of surgical cases as previously identified by MSAC has not been directly addressed.</p>
<p>MSAC concern whether podiatric surgeons provide the same level of service, particularly management of patient complications [PSD, p3]</p>	<p>The applicant has provided the ACPS Governance structure and Clinical Pathway for review in this application to outline the approach of the podiatric surgeon to holistic patient management, anticipation of complications and management of complication, with emphasis on inter-disciplinary communication.</p>
<p>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 [PSD, 3]</p>	<p>As outlined above, the applicant has relied on provision of the ACPS governance structure and clinical pathway, whilst emphasising inter-disciplinary communication and collaboration, to address this issue. The applicant has also provided a reference (Smith and Miller, 2019) that demonstrates a podiatric surgeon working in a multidisciplinary setting in an Australian public hospital.</p>
<p>Uncertainty about the package of care delivered to patients [PSD, p3]</p>	<p>The applicant stated that the complete package of care delivered to patients from podiatric surgery is equivalent to the comparator, from Australian and international evidence, and supported by provision of the ACPS governance structure and clinical pathway.</p>
<p>Cost analysis relies on assumption of non-inferiority to orthopaedic surgeons which was not established [PSD, p3]</p>	<p>No directly comparable evidence of clinical or safety outcomes for podiatric surgeons compared with orthopaedic surgeons for the eight clinical groupings for podiatric surgery in scope of this ADAR was provided.</p>

MSAC issues/recommendations based on MSAC 1344.1	How these recommendations have been addressed in 1344.2
Uncertain financial implications [PSD, p3]	Impacts on the MBS have been re-estimated to reflect the revised list of codes requested, updated methodology and new (and updated) data sources. Costs are provided under a 'low' and 'high' scenario to reflect current workforce trends for podiatric surgeons ('low' scenario) and higher levels of activity ('high' scenario) if MBS access attracts additional podiatric surgeons and enables current practices to expand their patient case load.

Source: *Compiled from Table 7, pp27-29 of the Critique*

MBS = Medicare Benefits Schedule; PSD = Public Summary Document; ACPS= Australasian College of Podiatric Surgeons; AIHW = Australian Institute of Health and Welfare; MSAC= Medical Services Advisory Committee.

## 5. Prerequisites to implementation of any funding advice

The ADAR stated that Podiatric Surgeons are podiatrists who have completed extensive postgraduate peri operative medical and surgical training in addition to a four-year undergraduate degree in podiatry. Podiatric surgeons currently operate in private practice (including private hospitals, day surgeries and office), with selected examples of public hospital activity, as (unlike in the United Kingdom and the USA) there are currently no public hospital podiatric surgical positions in Australia.

Podiatric surgeons provide a selection of procedures, such as surgery for:

- hallux valgus correction (equivalent MBS item(s) 49833, 49836 and 49821)
- management of Achilles tendon rupture in the ankle (equivalent MBS item 47921)
- subcutaneous tenotomy in the foot (equivalent MBS item 49806), and
- the correction of claw or hammer toe (equivalent MBS item 49848).

For these surgeries, podiatric surgeons service 30-52 per cent of the total case-load, noting that patients are accessing this surgery privately, without recourse to the MBS (Table 2).

**Table 2 Podiatric surgeons account for sizeable proportion of foot and ankle surgery caseload 2017**

Item	Clinical area	MBS (No. 2017)	ACPS Register (No. 2017)	Total activity (No. 2017)	Podiatric surgery share (%)
49833	1st MPJ	645	298	943	32
49848	Lesser toe	250	269	519	52
49836	1st MPJ	169	137	306	45
49806	Lesser toe	149	129	278	46
49821	1st MPJ	164	70	234	30
47921	Ankle	101	60	161	37

The ADAR noted that this was constructed based on assumed item-equivalent selection, which may vary by provider.

Source: Table 2, p22 of ADAR

ACPS = Australasian College of Podiatric Surgeons; MBS = Medicare Benefits Schedule; MPJ = metatarsophalangeal joint.

## 6. Proposal for public funding

The applicant has refined the set of MBS items to which the podiatric surgeons are seeking access to, in response to the request from MSAC that items be aligned to evidence of need and comparable safety and effectiveness with orthopaedic surgeons. There are 23 nominated surgical codes and five general codes included in this ADAR (Table 3).

**Table 3 MBS item descriptor for items proposed for access by podiatric surgeons**

<b>General</b>	<b>Description</b>
104	Professional attendance at consulting rooms or hospital by a specialist in the practice of his or her specialty after referral of the patient to him or her-each attendance, other than a second or subsequent attendance, in a single course of treatment, other than a service to which item 106, 109 or 16401 applies
105	Professional attendance by a specialist in the practice of his or her specialty following referral of the patient to him or her-an attendance after the first in a single course of treatment, if that attendance is at consulting rooms or hospital, other than a service to which item 16404 applies
51300	Assistance at any operation identified by the word "Assist." for which the fee does not exceed \$558.30 or at a series or combination of operations identified by the word "Assist." where the fee for the series or combination of operations identified by the word "Assist." does not exceed \$558.30
51303	Assistance at any operation identified by the word "Assist." for which the fee exceeds \$558.30 or at a series of operations identified by the word "Assist." for which the aggregate fee exceeds \$558.30
18272	SAPHENOUS, SURAL, POPLITEAL OR POSTERIOR TIBIAL NERVE, MAIN TRUNK OF, 1 or more of, injection of an anaesthetic agent
<b>Surgical</b>	
31350	BENIGN TUMOUR of SOFT TISSUE, excluding tumours of skin, cartilage, and bone, simple lipomas covered by item 31345 and lipomata, removal of by surgical excision, where specimen is sent for histological confirmation, on a person 10 year of age or over, not being a service to which another item in this Group applies
39330	NEUROLYSIS by open operation without transposition, not being a service associated with a service to which item 39312 applies
44359	ONE OR MORE TOES OF ONE FOOT, amputation of, including if performed, excision of one or more metatarsal bones of the foot, performed for diabetic or other microvascular disease, excluding aftercare
47915	IGTN, wedge resection for, with removal of segment of nail, unguinal fold & portion of nail bed
47916	INGROWING NAIL OF TOE, partial resection of nail, with destruction of nail matrix by phenolisation, electrocautery, laser, sodium hydroxide or acid but not including excision of nail bed
47918	Ingrown toenail, radical excision of nailbed
47930	BURIED WIRE, PIN OR SCREW, 1 or more of, which were inserted for internal fixation purposes, removal of requiring incision and suture, not being a service to which item 47927 or 47930 applies - per bone
47954	TENDON, repair of, as an independent procedure
47960	TENOTOMY, SUBCUTANEOUS, not being a service to which another item in this Group applies
48400	Phalanx, Met, accessory bone osteotomy or osteectomy (unless fixated toe applies)
48403	Phalanx or Met osteotomy or osteectomy of, with internal fixation
48406	FIBULA, RADIUS, ULNA, CLAVICLE, SCAPULA (other than acromion), RIB, TARSUS OR CARPUS, osteotomy or osteectomy of, excluding services to which items 47933 or 47936 apply
49709	ANKLE, ligamentous stabilisation of
49718	ANKLE, Achilles' tendon or other major tendon, repair of
49809	FOOT, open tenotomy of, with or without tenoplasty
49833	Unilateral HAV by osteotomy with or without internal fixation and with or without excision of exotoses
49836	Bilateral HAV by osteotomy with or without internal fixation and with or without excision of exotoses
49845	Arthrodesis of, 1st MT joint, with synovectomy if performed
49854	FOOT, radical plantar fasciotomy or fasciectomy of
49866	FOOT, neurectomy for plantar or digital neuritis

General	Description
50106	JOINT, stabilisation of, involving one or more of: repair of capsule, repair of ligament or internal fixation, not being a service to which another item in this Group applies
50109	JOINT, arthrodesis of, not being a service to which another item in this Group applies, with synovectomy if performed
50127	JOINT OR JOINTS, arthroplasty of, by any technique not being a service to which another item applies

Source: Table 1, pp12-13 of the ADAR

MBS items were selected on:

- 1) published clinical literature that demonstrates podiatric surgeons are already operating in all of these areas; however, the Commentary noted the most of these articles were case reports of a single patient, or small case series.
- 2) detailed statistical analysis comparing outcomes and patient characteristics for each item code when activity is performed by podiatric surgeons (ACPS Registry data) vs. orthopaedic surgeons (administrative datasets) from past four years
- 3) comparisons with government-funded podiatric surgery in the UK recorded by Podiatric and Surgical Clinical Outcome Measurement (PASCOS-10) for podiatric surgeons and podiatrists undertaking nail surgery in the UK for the NHS or private practice over the past 9 years; and
- 4) Australian podiatric surgery workforce survey data on the most commonly performed procedures.

The Commentary noted that the ACPS registry data in point 2 above was the best available evidence of current Australian practice, assuming mapping of MBS items to procedures has been undertaken robustly.

## 7. Summary of public consultation feedback/consumer Issues

Prior to MSAC consideration (and subsequent to the ESC), a total of 119 forms were received from the consultation survey (Table 4)

**Table 4 Summary of consultation feedback**

Attachment	Feedback type	Number of forms received
A	Feedback received by Groups / Organisations (including a submission from the Australian Orthopaedic Association)	10
B	Feedback received from Podiatrists and Podiatric Surgeons	43
C	Feedback received from Orthopaedic Surgeons	1
D	Feedback received from GPs, other Specialists, and other practitioners	16
E	Feedback received from consumers / patients of podiatric services	43
F	Feedback received from caregivers of patients	6

A summary of the benefits of the proposed medical service highlighted by groups/organisation are listed below:

- reducing out-of-pocket expenses for patients
- improving accessibility to foot/ankle surgery for patients
- diverting surgeries that can be managed out of the hospital system
- improving patient safety by allowing podiatric surgeons to refer patients to MBS subsidised specialists such as pathology and without basing the decision on affordability for the patient
- creating competition in the sector which will drive innovation
- improving the quality of life for patients.



The Australian Orthopaedic Association's (AOA) submission questioned the training, clinical experience and credentialing of podiatric surgeons in Australia. The AOA also raised concern regarding current outcomes and patient safety of podiatric surgeons and claimed surgery conducted by podiatric surgeons was associated with poorer outcomes compared to surgery conducted by orthopaedic surgeons. In relation to the later claim, the AOA referenced two publications by Chan (JBJC 2019 Jan 16; 101(2): 127 – 135 and Journal American Acad Orth Surg 15, 2019 vol 27, no 16). However, both these publications related to procedures that are out of scope for this application.

Some of the main benefits of the proposed medical service highlighted by podiatrists and podiatric surgeons included:

- less out-of-pocket costs and affordability for all patients, especially those who do not have private health insurance
- having equitable choice in surgeon performing the surgery of the feet/ankles
- better overall quality of life and mobility for patients
- reducing cost to society and burden on public health system
- private health insurers may consider covering podiatric surgery.

However, the following comments were also noted:

- There are few podiatric surgeons and patients will have reduced access especially in rural and regional areas
- *“Professional disputes [may arise] between podiatric surgeons and orthopaedic surgeons due to overlapping skill sets and patient cohorts”.*

Feedback from one orthopaedic surgeon, who also assisted in writing the AOA submission, considered there were no benefits of the proposed medical service and considered the disadvantages of the proposed service being listed would be *“inexperienced persons doing complex operations on vulnerable people”*. Consistent with the reasons provided in the AOA submission, this feedback did not support the application.

Some of the main benefits nominated by GPs, specialists and other practitioners included

- more equitable access for patients to foot surgery (*“[which is an issue particularly for those with] diabetes and peripheral vascular disease”*)
- affordability for all patients and lowering of out-of-pocket costs
- shorter wait times for both consultation and surgery for patient
- improvement in quality of life for patients.

However, the following disadvantages were noted in the proposed service:

- *“There will be a need for clarity in referral pathways for foot/ankle surgery between orthopaedic surgeons and podiatric surgeons”*
- *“Lack of accessibility to large hospital theatre facilities ...due to monopoly by orthopaedic surgeons”*
- *“Need of support at home while post procedure”*
- *“Short term recovery period”.*

Some of the main benefits of the proposed medical service highlighted by consumers included:

- better affordability to access podiatric surgery (it currently incurs high upfront costs and some patients used their savings to pay for surgery)
- acknowledging the high quality service delivered by podiatric surgeons (based on consumers perception that podiatric surgeons were more specialised than orthopaedic surgeons to perform surgeries on the feet/ankles)

- having equitable choice in surgeon performing the surgery of the feet/ankles
- improved accessibility to surgeons performing surgery of the feet/ankles
- better overall quality of life and significant improvement in mobility.

In general, the consumers did not express any disadvantages of the proposed medical service; however, the following was noted:

- There may be a large uptake in the service once MBS subsidised which may increase wait times for podiatric surgery services, but it may also reduce wait times for an orthopaedic surgeon
- *“Components of the service are not [currently] covered by private health”*
- Surgery of the feet/ankles normally follows 4 weeks or more of lost income due to being immobile and unable to work during recovery.

Some of the main benefits of the proposed medical service highlighted by caregivers included:

- better affordability in access to podiatric surgery for the patient
- patients can be treated sooner and not be disadvantaged due to costs as well as having treatment done on both feet simultaneously where needed and not being delayed
- having equitable choice in surgeon performing the surgery of the feet/ankles
- improvement in quality of life and mobility for the patient.

In general, the caregivers did not express any disadvantages of the proposed medical service.

## **8. Proposed intervention’s place in clinical management**

### **Description of Proposed Intervention**

The proposed medical service requested by podiatric surgeons includes a limited set of existing MBS codes for selected foot and ankle procedures, services and consultations to improve patient access to these surgical services in both the private and public sector.

### **Description of Medical Condition(s)**

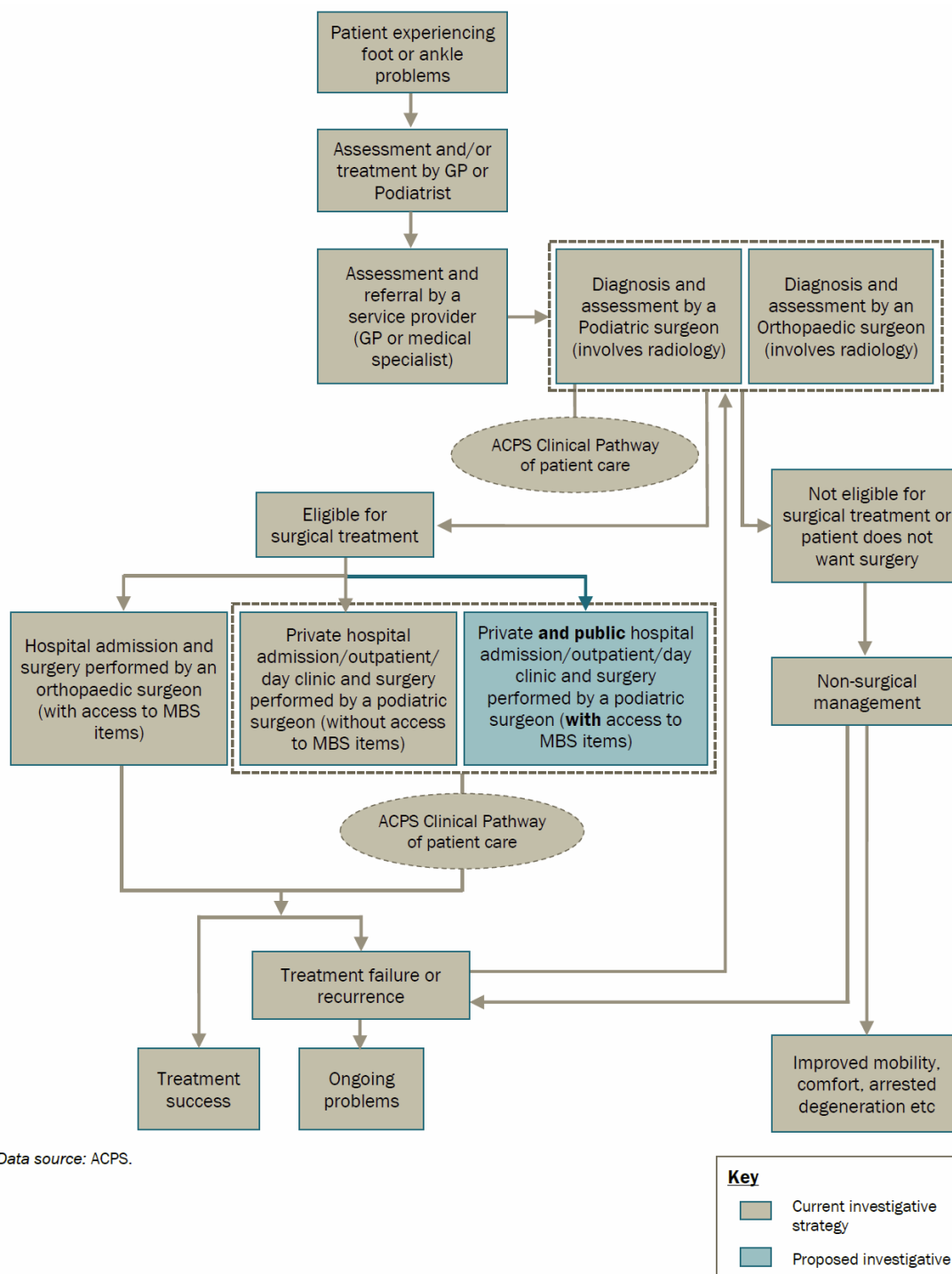
The conditions to which podiatric surgery relates correspond to eight clinical groupings:

- hallux abducto valgus (HAV)
- hammer and claw toes
- hind foot/ankle pathology
- ingrown toenails
- hallux rigidus
- arthritis
- nerve impingement, and
- tumour (benign).

No exclusion criteria were proposed, whether on the basis of age, severity or other factors.

### **Place in clinical management**

The ADAR’s current and proposed clinical management algorithm are presented in Figure 1.



Data source: ACPS.

**Figure 1 Clinical management algorithms**

Source: Figure 5, p37 of the ADAR.

The ADAR's clinical management algorithm is unchanged, except in two respects:

- For podiatric surgeons operating in a private hospital setting, outpatient clinic, day surgery centre or consultation room, there is no change to the clinical management algorithm aside from allowing access to MBS items for procedures that are otherwise (currently) fully funded by patients (in some cases, part funded by private health insurance). Hence the change relates to the cost-to-patients in private/community sectors where they already receive surgical services from a podiatric surgeon. There is no change to the clinical management algorithm for these patients.
- Unlike in the United Kingdom and USA, there are currently no funded positions for podiatric surgeons operating in Australian public hospitals. This could change if

podiatric surgeons were able to offer their services in public hospitals, as they currently offer them in other settings. This report points to Australian examples where podiatric surgeons have operated in public hospitals as part of a publicly funded study. It is noted that most of the MBS items are proposed to be for admitted (in-hospital) patients. Allowing MBS access to admitted public hospital patients would enable podiatric surgeons to service public hospital patients where there is evidence of non-inferiority to orthopaedic surgeons. This would constitute a change to the clinical management algorithm for admitted public hospital patients.

The Commentary stated that the ADAR is not proposing substitution of orthopaedic surgery services; accordingly, it has placed diagnosis and assessment by podiatric surgeons alongside orthopaedic surgeons in the clinical management algorithm. In addition, the Commentary noted there is no indication in the algorithm of interventions or therapies involved in the management of treatment failure or complications. However, in their pre-ESC response, the applicant indicated that the algorithm incorporates treatment of ‘ongoing problems’, which would be dealt with as part of normal patient management.

## **9. Comparator**

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

## **10. Comparative safety**

The ADAR sought to address previous MSAC concerns with the clinical evidence by providing an indirect database comparison of outcomes following foot and ankle surgery data from patients treated by podiatric surgeons from the ACPS registry over five years (n=8,142) vs. administrative data from patients treated by orthopaedic surgeons available from South Australia Health (n=9,337) and Tasmania Health (n=2,851). In addition, the ADAR included eight studies (9 publications) from literature review. Overall, the quality of available evidence is grade III-2, with data coming from administrative data, surveys or retrospective cohorts.

The ADAR stated that the safety of surgery undertaken by a podiatric surgeon can be shown to be non-inferior to that undertaken by an orthopaedic surgeon.

Complication rates: In literature review, the complication rate appears similar between the two surgeon types, although one report suggests malunion or non-union may be higher in podiatric surgery (ankle fracture repair) whilst another research project has identified that surgeon type was not associated with incidence of non-union (1<sup>st</sup> metatarsal [MT] joint arthrodesis).

Readmission rates: In literature review, no difference in readmission rates were reported in one retrospective cohort, although importantly, Australian evidence demonstrates a lower rate of readmission rates for podiatric surgery (occurring in < 3% of patients in the SA and Tasmanian data, and in 0.02% of podiatric surgeons’ patients). See Table 5 below.

The Commentary stated that the evidence of readmission rates included in the ADAR was not appropriate. This study investigated the impact (before and after) of the introduction of a podiatric high-risk foot coordinator role on length of stay (Chicero et al 2010). The study did not directly compare length of stay by surgeon type, nor did it declare that the podiatric high-risk foot coordinator role replaced the orthopaedic surgeon on the coordinated care team for which the inference of the findings attempts to be drawn.

## 11. Comparative effectiveness

The ADAR contends that effectiveness of surgery undertaken by a podiatric surgeon can be shown to be non-inferior to that undertaken by an orthopaedic surgeon.

Reason for surgery: In the database analysis, and several of the other analyses reported in the literature, reason for surgery was matched between surgeon type. The reason for surgery in the literature reflected the requested scope of practice for this submission.

Length of Stay: Of significance, length of stay in patients who undergo foot and ankle surgery with orthopaedic surgeons appears to be significantly longer than the length of stay reported in patients who undergo foot and ankle surgery with podiatric surgeons. This was also reflected in analysis of both the SA and Tasmanian datasets.

Patient preference: Patients appear to prefer surgery undertaken by a podiatric surgeon. Overall, the Commentary considered the quality of the evidence presented in the ADAR was very low quality (Table 5).

**Table 5 Balance of clinical benefits and harms of ankle and foot surgery performed by a podiatric surgeon, relative to foot and ankle surgery conducted by orthopaedic surgeons, and as measured by the critical patient-relevant outcomes in the key studies**

Outcomes	Participants (studies)	Quality evidence (GRADE)	of Podiatric Surgeons	Orthopaedic surgeons	Commentary
Malunion	1 study	⊕⊕⊖⊖	7.3%	4.6%	Limited applicability of patient (ankle surgery) population.
Infection	5 studies	⊕⊕⊖⊖	1.4% to 3.3%*	0.0% to 4.3%*	⊕⊖⊖⊖ No directly comparable recent evidence in relevant patient population.
DVT	3 studies	⊕⊕⊖⊖	0.4% to 3.2%*	0.0% to 3.1%*	⊕⊖⊖⊖ No directly comparable recent evidence in relevant patient population.
Irrigation and debridement	1 study	⊕⊕⊖⊖	2.2%	1.7%	Limited applicability of patient (ankle surgery) population.
Readmission	3 studies	⊕⊕⊖⊖	0.02% to 15.4%	1.8% to 17.2%	⊕⊖⊖⊖ No directly comparable recent evidence in relevant patient population.
Length of stay	3 studies	⊕⊕⊕⊖	1 -23 days	1 to 34 days	⊕⊖⊖⊖ No directly comparable recent evidence in relevant patient population. Inappropriate interpretation and application of Chicero (2013) study.

Adapted from Table 17, p69 of the ADAR. DVT = deep vein thrombosis

<sup>a</sup> GRADE Working Group grades of evidence (Guyatt et al., 2013)

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊖ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊖⊖ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕⊖⊖⊖ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

\* Lower and upper estimates across studies for reported outcomes included as lower and upper bound scenarios in economic modelling

The Commentary raised several concerns for the indirect database comparison:

- Reason for surgery is the indication for treatment and is not an appropriate outcome measure.
- Concern with comparability of these separate datasets, due to differences in their purpose, collection and methods, and deficiencies in mapping of ICD-10 codes to MBS items relating to foot and ankle surgery. It is unclear how overlapping codes were handled in the analysis, and there is concern about quality of matching ICD-10 codes to MBS items (for example, within the South Australian and Tasmanian government data sets, ICD M77.4 “metatarsalgia” is matched to MBS item 49485 “arthrodesis of 1st metatarsal joint”; these are different clinical entities). In their pre-ESC response, the applicant acknowledged this is not an entirely perfect approach; however, the method adopted provides the best possible matching given the available data.
- There was significant differences in treatment setting noted between the groups, 95.5% of podiatric surgeon patients undergoing day surgery compared to 70% of orthopaedic patients, and there was no discussion of complexity of pathology between the groups, nor differences in case mix. For example, the most common procedure in the podiatric surgery group was hallux valgus at 30.86%, compared to 5.72% in the Tasmanian orthopaedic group and 14.99% in the South Australia orthopaedic group. However, in their pre-ESC response, the applicant stated the higher rate of day admissions for podiatric surgeons reflects the high level of innovation in peri-operative and operative care provided by podiatric surgeons.

In their pre-MSAC response the applicant highlighted that unadjusted analyses was presented for the indirect database comparison due to the different reporting requirements between the state-based data and the ACPS Registry. Thus, the applicant considered the indirect database comparison to be supportive evidence for the clinical claim of non-inferiority.

The Commentary also raised several concerns for the included studies from literature review:

- Chan et al, 2018 study was the only directly comparable registry-based study; however, this was limited in terms of applicability given the less relevant patient population (ankle surgery) included and the US setting.
- Cichero (2013) study which was included as an efficacy (length of stay) outcome measure does not include a comparison of podiatric and orthopaedic surgery outcomes, but rather illustrates the utility of a high-risk foot coordinator in improving the patient journey.

### **Clinical claim**

The ADAR stated that for the eight clinical groupings specified, podiatric surgeons are at least non-inferior to orthopaedic surgeons in terms of clinical safety and efficacy in undertaking foot and ankle surgery and associated pre-operative and post-operative care.

Overall, the Commentary stated the evidence base in support of the ADAR is significantly limited by the lack of prospective, comparative, large scale, robust studies; the persistence of heterogeneity of reported outcome measures in the existing foot and ankle surgery literature; and sometimes dated evidence.

In their pre-MSAC response the applicant highlighted given that, currently there is no Australian clinical setting where orthopaedic and podiatric surgeons work together, the lack of directly comparable evidence is unsurprising.

## 12. Economic evaluation

The ADAR concluded non-inferiority from the clinical evaluation, and presented a cost-minimisation analysis (Table 6). Based on the indirect database comparison, the upper and lower bound probabilities of infection and deep vein thrombosis (DVT) by surgeon type are used to estimate upper and lower bound economic outcomes. However, the Commentary noted that rates of infection and DVT were not significantly different in some studies (Chan et al. 2018; Laxton, 1995), and were also specific to ankle fractures (Chan et al. 2018), and their inclusion in the model is uncertain (given irrigation and debridement were excluded on the basis of lack of statistically significant difference, and malunion was excluded as the evidence was specific to ankle fractures and that the MBS item numbers being requested do not explicitly relate to ankle surgery).

**Table 6 Summary of the economic evaluation**

Perspective	Cost of treatment and cost of managing adverse events
Comparator	Comparable surgery undertaken by an orthopaedic surgeon
Type of economic evaluation	Cost-minimisation
Sources of evidence	Clinical Evaluation Systematic Review, MBS, ACPS Register
Time horizon	One treatment episode
Outcomes	Cost per treatment episode
Methods used to generate results	Expected value analysis
Discount rate	NA (time horizon is less than 1 year)
Software packages used	Microsoft Excel 2016

Source: Table 19 of the ADAR

ACPS = Australasian College of Podiatric Surgeons; MBS = Medicare Benefits Schedule

The ADAR stated prosthesis use, and cost per use, by surgeon type is based on data from HBF for all surgeries undertaken by a podiatric (n=666) or orthopaedic surgeon for six MBS items in 2015-16, 2016-17, and 2017-18. However, the ADAR acknowledged the applicability concerns using HBF data on surgeries from a subset of the MBS requested item codes (6/23 surgical items). The cost of the requested MBS item was also not included in the economic model, as the relevant MBS item and its respective cost would be the same whether delivered by a podiatric or orthopaedic surgeon.

The Commentary stated that the cost-minimisation analysis is driven by the higher cost of prosthetics used by orthopaedic surgeons (Table 7).

**Table 7 Complication management resource use and costs used in the economic evaluation**

Service	Intervention: Podiatric surgeon	Comparator: Orthopaedic surgeon	Increment
<b>Lower bound scenario</b>			
Prosthesis	\$162	\$811	-\$650
Infection	\$3	\$0	\$3
DVT	\$1	\$0	\$1
<b>Total cost/patient</b>	<b>\$165</b>	<b>\$811</b>	<b>-\$646</b>
<b>Upper bound scenario</b>			
Prosthesis	\$162	\$811	-\$650
Infection	\$6	\$8	-\$2
DVT	\$5	\$5	\$0
<b>Total cost/patient</b>	<b>\$174</b>	<b>\$825</b>	<b>-\$651</b>

Source: Table 26, p77 of the ADAR. DVT = deep vein thrombosis

The Commentary stated that prosthesis use, and cost per use, by surgeon types as provided by HBF Health is inherently biased by differences in accessibility to these services, including private health insurance coverage. Substantially fewer and likely less complicated procedures were performed by podiatric surgeons compared to orthopaedic surgeons consequently resulting in significantly lower costs per service (\$460 vs. \$1,593, respectively).

In the pre-ESC response, the applicant indicated that the major difference in costs in the HBF data is due to the prosthesis use and the fact that podiatric surgeons are more likely to admit their patients as day cases (relative to orthopaedic surgeons); it is not related to orthopaedic surgeons doing more complex work. In the pre-MSAC response, the applicant highlighted that the HBF states ‘the prosthesis use was mapped on a like for like basis in relation to the provided MBS item numbers specific for the most common procedures performed in the foot and ankle.’

The Commentary also considered the generalisability of the HBF dataset in terms of estimating prosthesis use is limited given that this data is restricted to Western Australia. Furthermore, whilst the data have been matched according to the MBS codes, there is no further discussion of the comparability of the groups, matching for demographics, comorbidity, severity of pathology etc. In addition, the applicant only included costs associated with identifying complications and not included additional MBS and PBS costs associated with management of DVT and infection.

The ADAR’s sensitivity analysis, which compared the poorest potential performance of a podiatric surgeon with the best potential performance of an orthopaedic surgeon still shows that podiatric surgery is cost-minimising against orthopaedic surgery (Table 8). The Commentary did not perform additional sensitivity analyses given the uncertainty in the clinical and economic evidence base and the inability to undertake meaningful economic analysis.

**Table 8 Complication management resource use and costs used in the economic evaluation**

Service	Intervention: Podiatric surgeon	Comparator: Orthopaedic surgeon	Increment
<b>Poorest performance by podiatric surgeon scenario</b>			
Prosthesis	\$162	\$811	-\$650
Infection	\$6	\$0	\$6
DVT	\$5	\$0	\$5
<b>Total cost/patient</b>	<b>\$174</b>	<b>\$811</b>	<b>-\$638</b>

Source: Table 27, p77 of the ADAR. DVT = deep vein thrombosis

### 13. Financial/budgetary impacts

An epidemiological approach was used to estimate the financial implications of allowing podiatric surgeons to access 23 surgical MBS item numbers and five general items. Data sources used to inform the derivation of the financial implications included the ACPS Registry database to inform volume and growth of expected services on the MBS, weighted average MBS cost for 23 requested surgical items, and assumptions based on expert opinion reflecting consensus amongst four podiatric surgeons, each with at least 15 years of surgical experience.

Rather than providing a base-case estimate, the ADAR provided financial estimates for two scenario analyses:

- The ‘low’ scenario is based on the current podiatric surgeon workforce in the first year and forecast workforce trends as reported in the ACPS 2019 survey of the



podiatric surgeon workforce. In their pre-MSAC response, the applicant highlighted that in this scenario it is modelled that there will be one new podiatric surgeon able to join the workforce each year, net of any new entrants and retirements.

- The ‘high’ scenario assumed that MBS access attracts additional podiatric surgeons and enables current practitioners to expand their patient case load. This scenario was provided in response to an inquiry from the Department of Health that MBS listing might result in an expanded podiatric surgeon workforce (Table 9). In their pre-MSAC response, the applicant highlighted that in this scenario it is modelled that there will be three new podiatric surgeons able to join the workforce each year, net of any new entrants and retirements.

The ADAR stated that both scenarios assume there is no substitution in activity with orthopaedic surgeons, and all podiatric surgery for the 23 requested MBS items represents a new cost to the MBS. The Commentary stated this was appropriate given that the underlying contention of the application is to supplement unmet demand and not to replace existing services.

**Table 9 Net cost to the MBS**

<b>‘Low’ scenario</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
Number of services*	11779	13531	14242	14963	15694
General items: total services <sup>a</sup>	8743	10024	10544	11071	11606
Surgical items: total services <sup>b</sup>	3037	3507	3698	3891	4088
Requested procedures	\$1,311,018	\$1,508,910	\$1,589,113	\$1,670,520	\$1,753,148
Imaging	\$79,585	\$91,916	\$96,914	\$101,987	\$107,136
Pathology	\$14,073	\$16,254	\$17,138	\$18,035	\$18,945
Anaesthetist	\$159,920	\$184,699	\$194,742	\$204,936	\$215,282
<b>Sub- total cost</b>	<b>\$1,564,596</b>	<b>\$1,801,779</b>	<b>\$1,897,907</b>	<b>\$1,995,477</b>	<b>\$2,094,511</b>
<b>‘High’ scenario*</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
Number of services*	11779	13531	15074	16617	18160
General items: total services	8743	10024	11153	12282	13410
Surgical items: total services	3037	13507	3921	4336	4750
Requested procedures	\$1,311,018	\$1,508,910	\$1,683,140	\$1,857,370	\$2,031,600
Imaging	\$79,585	\$91,916	\$102,773	\$113,630	\$124,488
Pathology	\$14,073	\$16,254	\$18,174	\$20,094	\$22,014
Anaesthetist	\$159,920	\$184,699	\$206,516	\$228,333	\$250,149
<b>Sub-total cost</b>	<b>\$1,564,596</b>	<b>\$1,801,779</b>	<b>\$2,010,603</b>	<b>\$2,219,427</b>	<b>\$2,428,251</b>

Source: Table 43, p92 of the ADAR and Financial implication spreadsheet

MBS = Medicare Benefits Schedule

<sup>a</sup> MBS items 104, 105, 51300, 51303, 18272

<sup>b</sup> MBS items 49809, 49866, 47915, 47918, 31350, 48400, 49845, 48403, 47954, 50127, 39330, 50106, 47930, 48406, 49854, 47916, 49836, 49833, 44359, 49709, 49718, 47960, 50106.

\*Note differences due to rounding

The ADAR stated that a major driver of the cost differential between the low and high scenario is the number of new patients that will be seen by a podiatric surgeon, who incur a 104 professional attendance item. The ADAR did not perform additional sensitivity analysis, outside the two scenario analyses presented. The Commentary stated that given the substantial uncertainty in the evidence and assumptions included in the analysis, sensitivity analysis or further substantiation of the subjective inputs in particular ACPS and expert opinion, is recommended.

The ADAR did not identify any financial implications for other parts of the Australian health budget. However, the Commentary considered that it is likely there would be further costs to state governments in the event podiatric surgeons, with access to MBS items, are able to take up practice in public hospitals (an aim of this ADAR). In this setting there would be administrative costs, costs associated with operation of the operating theatre, and for those patients requiring an inpatient admission (i.e. not suitable for day surgery) there would likely be involvement of resident medical staff in the pre- and post-operative periods.

The Commentary also stated with an increased volume of foot and ankle surgeries being performed if podiatric surgeons are able to access MBS items (the ADAR assumes no substitution of orthopaedic services), inherently there will be a greater number of surgical complications that require management, the examples in this ADAR being infection and DVT. If a podiatric surgeon is unable to manage a post-operative infection, they would be required to refer for consultation with a medical practitioner. This may attract additional MBS items, as well as PBS items during the management of the infection, incurring additional costs. These were not included in the financial analysis.

In the pre-MSAC response, the applicant highlighted that the financial estimates to the MBS are very conservative with the MBS impacts essentially hinging on expected patient numbers that are ‘new’ to the MBS.

#### 14. Key issues from ESC for MSAC

##### Summary of key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Justification for a discrete set of MBS items relevant to current scope of practice for podiatric surgeons	The Applicant presented published clinical literature of podiatric surgeons operating in the relevant areas for each of the 23 MBS surgical items requested. The proportion of podiatric surgery procedures that cover the 23 requested MBS items was 66% (assuming mapping robustness). Limited contemporary Australian evidence is available for the comparator treatments. The other available evidence, including from overseas sources, is lower quality than the ACPS registry data.
Unmet need for podiatric surgeons’ services	The Applicant presented orthopaedic surgery waiting times from the AIHW and increasing demand for services data through MBS claims data. However, this does not necessarily represent an unmet need for podiatric surgeons. It was unclear whether the wait times related to the 23 proposed MBS items or to the 8 clinical groupings for these items.
Evidence of non-inferiority to orthopaedic surgeons	Given the lack of directly comparable evidence for safety and effectiveness, non-inferiority could not be established. However, ESC noted that this also does not show that services provided by podiatric surgeons are inferior to those provided by orthopaedic surgeons.
Impacts on the MBS of accessing those items for which there is demonstrated non-inferiority to orthopaedic surgeons	The financial implications analysis was based on more plausible assumptions and data, namely MBS claims data and ACPS registry data (not comparative). However, given that claims of non-inferiority were not supported in the clinical evaluation, the financial implications for the MBS remain uncertain.
Assurance about the complete package of care delivered to patients, including the ability of podiatric surgeons to work in multidisciplinary teams	There is little evidence that podiatric surgeons incorporate holistic patient care or liaise with other health professionals for best practice care, nor sufficient evidence regarding multidisciplinary team care provided by podiatric surgeons.

ACPS= Australasian College of Podiatric Surgeons; AIHW = Australian Institute of Health and Welfare; ESC = Evaluation Sub-Committee  
MBS = Medicare Benefits Schedule; MSAC= Medical Services Advisory Committee  
ESC discussion

ESC noted the five key issues that MSAC had requested be addressed in this resubmission:

- Justification for a discrete set of MBS items relevant to current scope of practice for podiatric surgeons
- Evidence of unmet need for podiatric surgeons' services
- Evidence of non-inferiority of outcomes between services delivered by podiatric surgeons compared to same services delivered by orthopaedic surgeons
- Impacts on MBS expenditure of extending access to podiatric surgeons for those items for which there is demonstrated non-inferiority in outcomes
- Assurance about the complete package of care delivered to patients, including the ability of podiatric surgeons to work in multidisciplinary teams.

ESC noted the revised set of MBS items requested by the applicant, including 23 surgical codes and 5 general codes, leading to 8 clinical groupings. Evidence to support this request was primarily data from the ACPS registry, which ESC considered was the best available evidence of current Australian practice for podiatric surgeons. The proportion of podiatric surgery procedures that cover the 23 requested MBS items was calculated as 66%, assuming that the mapping of ICD-10 codes for procedures at the state level to MBS items at the national level was robust. Evidence from published literature was also presented, but ESC considered this to be of lower quality than ACPS registry data, and noted that international data may not be applicable to the Australian context.

Regarding unmet need, ESC noted the evidence presented on public hospital wait times for elective orthopaedic surgery of the foot and ankle, workforce shortages of orthopaedic surgeons, strong underlying demand for foot and ankle surgeries, and the 'capping out' of existing podiatric surgery demand as patients are deterred by high out-of-pocket costs. ESC considered that this evidence did not necessarily represent an unmet need for podiatric surgeons, although noted that wait times can be used to indicate the lower bound of people who would use the services. ESC queried whether the applicant's assessment of wait times (Table 10) was accurately represented by the 8 clinical groupings or the 23 MBS items, and requested that this issue is clarified by the applicant, and wait times assessed for the 23 individual MBS items, before the submission is heard by MSAC.

**Table 10 Wait times for foot and ankle surgeries in Australian public hospitals 2016-17**

<b>Surgery type</b>	<b>Waiting period (days)</b>
Excision of exostosis	229
Removal of Bunion (hallux valgus)	169
Excision of ganglion	93
Osteotomy	84
Change of muscle or tendon length	82
Correction of hammer/claw/mallet toe	63
Toenail surgery	40

Source: Table 6, p29 of the ADAR. Data source: CIE analysis; Australian Institute of Health and Welfare, 'Waiting times for elective surgery', available at: <https://www.aihw.gov.au/reports/hospitals/elective-surgery-waiting-times-ahs-2015-16/contents/table-of-contents>.

ESC noted two minor changes relating to the clinical management algorithm compared to the previous submission. First, for podiatric surgeons operating in a private hospital setting, outpatient clinic, day surgery centre or consultation room, there was no change to the clinical management algorithm, but there was a change relating to the cost to patients. Second, for podiatric surgeons operating in a public hospital setting (which they currently do not), the

clinical management algorithm was changed to allow MBS access to admitted public hospital patients.

ESC noted the clinical claim that patient outcomes in terms of clinical safety and efficacy when undertaking foot and ankle surgery and associated pre-operative and post-operative care are at least non-inferior where a service is delivered by a podiatric surgeons compared to an orthopaedic surgeon. ESC also noted the resubmission's evidence relied upon a selection of cohort studies, retrospective cohort studies, audits, and commissioned analysis of health data sources.

To address previous MSAC criticism of lack of Australian evidence, the resubmission's key evidence was an indirect comparison of outcomes for patients treated by podiatric surgeons from the ACPS registry (n=8,142) over the past 5 years with administrative data from patients treated by orthopaedic surgeons available from South Australia Health (n=9,337) and Tasmania Health (n=2,851). ESC queried if the orthopaedic data from Tasmania and South Australia was a nationally representative sample, but agreed with the applicant pre-ESC response claim that these datasets provide the best available Australian evidence.

However, ESC considered the indirect comparison was weakened by the comparability of the separate datasets in the analysis, due to differences in purpose, collection and methods and matching issues arising with mapping International Classification of Disease version 10 (ICD-10) codes to MBS items relating to foot and ankle surgery. ESC noted in their pre-ESC response, the applicant also acknowledged the limitations of this matching approach. In addition, the applicant considered with greater availability of data, comparisons could have been adjusted for comorbidities or diagnosis, which was difficult due to different reporting requirements between state based data and the ACPS registry. ESC also considered that the data were subject to risk of reporting bias, and was limited by the short 30-day follow-up for safety or patient effectiveness outcomes. In addition, statistical significance or relative differences in outcomes was not reported except for length of stay, interpretation of which is substantially limited given differences in access to and complexity of procedures (e.g. day case vs. admitted) performed by surgeon type, which was not adjusted for in the statistical analysis.

ESC noted the overall quality of the other included studies is very low, with high risk of bias. ESC considered some of the outcome measures selected to assess comparative effectiveness and safety are deficient in terms of relevance to the clinical question, such as reason for surgery as a comparator of effectiveness between podiatric and orthopaedic surgeons, or in their subjective nature, such as patient and General Practitioner satisfaction with care provided by podiatric and orthopaedic surgeons respectively. The age of some of the included studies also raised concern with relevance to contemporary practice. In addition, ESC noted only one directly comparable registry-based study was identified (Chan et al. 2018) and this was limited in terms of applicability given the out of scope patient population (ankle surgery) included and the country (United States) setting.

Overall, ESC concluded that, given the lack of directly comparable evidence for safety and effectiveness, non-inferiority could not be established. However, ESC noted that this also does not show that services provided by podiatric surgeons are inferior to those provided by orthopaedic surgeons.

Regarding the complete package of care provided by podiatric surgeons, ESC again noted that there is little evidence that podiatric surgeons incorporate holistic patient care or liaise with other health professionals for best practice care. ESC also noted that the resubmission's evidence demonstrating podiatric surgeons are able to work in multidisciplinary team

environments relied on the provision of ACPS governance structure and clinical pathway and a prospective case series involving 23 patients with diabetes, who underwent minimally invasive tenotomy procedures (Smith and Miller 2019). While ESC acknowledged this study illustrates podiatric surgeons working within a multidisciplinary environment in an Australian public hospital, the research is not generalisable to podiatric surgery, given its focus on a single procedure, in a relatively small patient population, in the outpatient setting only, at a single centre.

ESC noted the economic evaluation assessed the cost of treatment and managing adverse events in one treatment episode. ESC noted the data source was a private health insurer, and considered that these data were potentially biased regarding management of complications. The main driver was the cost of a prosthesis, which was substantially lower for podiatric surgeons (\$162) than for orthopaedic surgeons (\$811). ESC also noted the applicant in their pre-ESC response reasoned that the major differences in costs in the HBF data is due to prosthesis use and the fact that podiatric surgeons are more likely to admit their patients as day cases than orthopaedic surgeons. However, ESC considered that the applicant did not address issues relating to translation of the clinical evidence. The resubmission also did not provide information about how underlying differences in the comparisons were controlled for, such as complexity of services, length of stay and service accessibility (including private health insurance).

ESC noted the financial implications for the MBS included a 'low' scenario based on current workforce and forecast workforce trends over 5 years, and a 'high' scenario that assumes a growing workforce of podiatric surgeons. No sensitivity analysis was performed. ESC noted that other potential costs were not included in the analysis, such as administrative and other costs for public hospitals associated with podiatric surgeons taking up practice in public hospitals, and increased surgical complications due to higher volume of surgeries performed (which would increase costs and potentially involve other MBS or PBS items). ESC concluded that the financial analysis was based on plausible assumptions and data (non-comparative MBS claims data and ACPS registry data); however, given the clinical claim of non-inferiority could not be substantiated, the financial implications for the MBS remain uncertain.

ESC noted there was no consumer input for this resubmission.

Consistent with previous MSAC advice for Applications 1344 and 1344.1, ESC noted it was beyond the remit of MSAC to comment on scope of practice or provide an assessment on competencies and accreditation standards of podiatric surgeons, as Health Technology Assessment methodologies are not designed to answer credentialing questions. The ESC noted these activities are the remit of the Australian Health Practitioner Regulation Agency (AHPRA).

## **15. Other significant factors**

Nil.

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

The College is extremely disappointed about MSAC's recommendation, particularly given that the ADAR addressed in detail specific issues identified by MSAC utilising the data sources they recommended as well as additional data sources. The College notes that MSAC did not identify any specific concerns with the potential inclusion of podiatric surgery within the MBS and the College has provided significant evidence that stands up to the rigorous

challenges set by MSAC. Further, the PSD places too much consideration on two submissions from the AOA and one individual orthopaedic surgeon compared to the data acknowledged by MSAC as the ‘best available Australian data’ (p.3) and considerable positive consumer input. The College does not accept MSAC’s consideration that the evidence for unmet need in regards to foot and ankle surgery is unclear, particularly given that the comparator for this is orthopaedic procedures not the MBS as a whole, and notes that the expenditure associated with this application was significantly lower than the \$6 million earlier identified as ‘moderate’ in the *Critique Report* for Application 1344 (p.36). The College also appreciates the acknowledgement that the lack of directly comparable evidence for safety and effectiveness is ‘primarily because of the paucity of high-quality contemporary evidence for the safety and effectiveness of the services delivered by orthopaedic surgeons (relative to the evidence that is available for podiatric surgeons from the ACPS registry’ (PSD, p.3). MSAC also acknowledges that this does ‘not necessarily mean that services provided by podiatric surgeons are inferior to those provided by orthopaedic surgeons’.

The College notes MSAC’s comments about a discrete set of MBS item numbers for podiatric surgeons and that this is ‘primarily a policy and administrative issue for the Department’ (p.3). The College looks forward to working with the Department to investigate this further, particularly considering the *Critique Report*’s comment that supporting this Application would facilitate delivery of an equivalent package of care to patients and ‘serve the public interest in a responsible manner’ (p.56).

## **17. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)