

# Medical Services Advisory Committee (MSAC)

## Public Summary Document

### *Application No. 1711 – Review of MBS items for subacromial decompression*

**Applicant:** Australian Government Department of Health and Aged Care

**Date of MSAC consideration:** 30-31 March 2023

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

#### 1. Purpose of application

MSAC requested the Department of Health and Aged Care undertake an evidence review of the safety, effectiveness, and cost-effectiveness of subacromial decompression (SAD) to ensure government funding on the Medicare Benefits Schedule (MBS) in Australia is based on strong evidence of clinical and cost effectiveness.

The [Terms of Reference](#) for the review were endorsed by MSAC following consultation with stakeholders.

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

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC did not support the continued public funding of subacromial decompression (SAD) as a standalone procedure in adult patients with symptomatic subacromial shoulder impingement. MSAC considered that SAD is less safe than active conservative management in the short term as it involves general anaesthesia and the risk of peri-operative complications. MSAC considered there was insufficient evidence to show SAD was more effective than active conservative management and that high certainty in the evidence demonstrated that SAD had no clinically important benefits over placebo (sham) procedure. Therefore, MSAC considered that because SAD has inferior safety, noninferior effectiveness compared with active conservative management or placebo (sham) procedure, and, as it is more expensive, SAD could not be cost-effective. MSAC noted the financial implications associated with disinvestment of SAD as a standalone procedure on the MBS. MSAC advised that consultation with stakeholders and patient groups, noting the recommendations made previously by the MBS Review Taskforce Orthopaedic Clinical Committee, would be important before any changes are implemented.

#### Consumer Summary

This application was a request from MSAC to conduct an evidence review of the safety, effectiveness and cost-effectiveness (value for money) of Medicare Benefits Schedule (MBS) items of subacromial decompression in Australia.

This application is a review of current and proposed items on the MBS for subacromial decompression.

## Consumer Summary

Subacromial decompression is a type of shoulder surgery. The procedure involves removing bone or soft tissue that causes narrowing of the subacromial space (a space between the bones and ligaments in the shoulder joint) that can cause impingement of soft tissues. It is used to treat certain types of weakness and pain in a person's shoulder, if they are not getting better after at least 6 months of active conservative management. Active conservative management (non-surgical therapy) includes treatments such as physiotherapy, exercise therapy, medications, shoulder injections, and rest.

MSAC reviewed the clinical trials that compared subacromial decompression with active conservative management. Overall, there were no clear differences between subacromial decompression and active conservative management when it comes to people's shoulder pain, shoulder function, or health-related quality of life. This means that there is little or no evidence that subacromial decompression works better than active conservative management. In the short-term the surgery is not as safe as active conservative management, although serious side effects are rare.

MSAC considered that continuing to fund subacromial decompression under the MBS would not be appropriate. This is because patients would be exposed to potential harms from the surgery for no meaningful benefit beyond what could be gained from active conservative management, and the health system would keep spending public money on something that offers minimal benefit.

MSAC noted that removing these items from the MBS could increase out-of-pocket costs for some patients. MSAC advised that it will be important to consult with stakeholders and patient groups before any changes are made.

### **MSAC's advice to the Commonwealth Minister for Health and Aged Care**

MSAC did not support continued listing of subacromial decompression on the MBS. This was because there is evidence that subacromial decompression works no better and is less safe than active conservative management. As such it is also not value for money.

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

MSAC noted that the purpose of the application was an evidence review of the safety, effectiveness, and cost-effectiveness of subacromial decompression (SAD). MBS items for SAD, surgery and rotator cuff repair are commonly performed in Australia and are currently reimbursed through the MBS. In 2019, the MBS Review Taskforce Orthopaedic Clinical Committee recommended that for shoulder surgery, existing items for SAD and rotator cuff repair should be consolidated (recommendation 74, 75)<sup>1</sup>. However, these recommendations were not implemented with the suite of orthopaedic changes on 1 July 2021, pending the outcome of the review of subacromial decompression services.

MSAC acknowledged that the consolidated items for SAD and rotator cuff repair recommended by the MBS review represent what is seen as professional best practice.

MSAC noted there is currently significant utilisation of MBS items 48900, 48903 and 48951, and that stakeholder groups had raised concerns about patient access to best practice conservative care during the consultation process.

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<sup>1</sup> <https://www.health.gov.au/resources/publications/taskforce-final-report-orthopaedic-mbs-items>

MSAC noted that the PICO-rated population is adult patients with symptomatic subacromial shoulder impingement and unresolved symptoms despite conservative therapy for 6 months. In this population, SAD is used as a standalone procedure, performed as an open or arthroscopic procedure. MSAC noted that following PASC advice, the use of SAD in addition to surgery for rotator cuff repair was removed from the scope of this review.

MSAC noted the current and proposed MBS items for SAD as a standalone procedure (see Table 2) do not nominate a proposed population. During consultation, the Shoulder and Elbow Society of Australia (SESA), recommended that patient selection for acromioplasty (surgery that treats shoulder impingement and rotator cuff disease of which SAD is one form) should be:

- A failure of nonoperative measures over 4–6 months
- Examination consistent with impingement and with the exclusion of other common causes of shoulder pain such as adhesive capsulitis, long head of biceps tendonitis, osteoarthritis etc.
- Ongoing untenable symptoms
- The demonstration of a mechanical cause for the cuff impingement (e.g. radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion).

MSAC noted the comparator – continued active conservative management (i.e. non-surgical therapy) – includes rest or no treatment, medication for pain and inflammation, physiotherapy, and subacromial injection.

MSAC noted that a total of 17 studies (including 9 randomised controlled trials [RCTs] and 5 case series met the inclusion criteria for assessing the safety and effectiveness of SAD compared with active conservative therapy. Two trials had a low risk of bias, but others had a higher risk of bias due to a lack of protocol, a lack of information regarding randomisation, an inability to blind across treatment populations, and imbalances across reported populations at follow-up.

MSAC noted the data on comparative safety (see Table 4), which indicate that adverse event rates are broadly similar for SAD, active conservative management and placebo (sham) procedure. However, MSAC considered that given SAD also involves general anesthesia and the risk of peri-operative complications that SAD is less safe than active conservative management in the short term and likely non-inferior in the long term. MSAC agreed with ESC that SAD has an inferior safety profile compared with active conservative therapies, but serious adverse events are rare.

MSAC noted the data on comparative effectiveness. Overall, low to moderate certainty evidence showed there were no clear differences in outcomes between SAD and active conservative management relating to shoulder pain, shoulder function and health-related quality (see Table 8). Rather, the strongest evidence shows that SAD does not provide clinically important benefits over placebo (sham) procedure in the outcomes of pain, function or health-related quality of life (see Table 9). MSAC noted that the trial populations may reflect a broad, heterogeneous population of patients who were not selected based on defined criteria of pain or function. MSAC concluded that it was not possible from the study results to determine whether a subpopulation of patients may benefit from SAD. MSAC considered that SAD had noninferior effectiveness compared with active conservative management or placebo (sham) procedure.

MSAC noted the suggestion from ESC that a potential patient population may be those who have undergone active conservative management for 6 months with no improvement and who have radiological evidence of a mechanical cause of impingement (preferably using magnetic resonance imaging [MRI] as the gold standard). However, MSAC noted that there were no studies that indicate that these patients would benefit from SAD. MSAC noted that the purpose of SAD or other interventions is to reduce the patient's pain. The high sensitivity of MRI may result in

incidental findings that may not be related to shoulder pain. It was suggested that radiological findings are equally as common in patients with and without symptoms, meaning that it is not possible to determine whether these findings are related to pain. MSAC therefore did not consider MRI evidence of mechanical impingement to be a reliable criterion for a subpopulation that would benefit from SAD.

MSAC also considered that the clinical evidence suggests that the natural history of SAD is likely to be an important factor and if so, that the duration of the condition is likely irrelevant to recovery, as recovery occurs unpredictably in the population. This explanation would be in keeping with other regional musculoskeletal conditions such as lateral elbow pain (i.e. persistent tennis elbow; Ikonen et al. 2021)<sup>2</sup>.

MSAC noted that, more broadly, there is limited evidence demonstrating the efficacy of exercise therapy/physiotherapy interventions (included in the comparator) in the management of rotator cuff disease. MSAC noted the results from the GRASP trial<sup>3</sup> which demonstrated that a progressive exercise therapy program was not superior compared with best-practice physiotherapy management (single session, advice focused), with or without corticosteroid injection for the treatment of patients with rotator cuff disorders (including impingement syndrome).

MSAC noted the economic evaluation was a cost comparison, based on the framework of a cost-minimisation approach of SAD compared with active conservative management. The cost comparison shows that the management of subacromial impingement is more expensive when SAD is involved in all scenarios. MSAC noted the issues raised by ESC for the economic model and agreed that it was not useful for decision making.

MSAC considered the financial and budgetary analysis (see Table 12). The base case scenario indicated a cost to the MBS of \$6.9 million in 2022, reducing to \$3.7 million in 2027. MSAC noted there is a decreasing trend in the number of patients receiving SAD services on the MBS in the past 5 years and a similar trend is also observed in Australian hospital data related to the principal diagnosis of subacromial impingement. MSAC agreed with ESC's assessment that the financial analysis is limited by the fact that only 20% of physiotherapy sessions are claimed through the MBS, so total costs associated with active conservative management are likely to be underestimated. MSAC noted that all four alternative scenarios produced to capture potential modifications of the SAD service scope in the financial and budgetary analysis result in net cost savings to the MBS compared to current practice.

Overall, MSAC considered there was insufficient evidence that showed SAD was more effective than active conservative management and that high certainty in the evidence demonstrated that SAD had no clinically important benefits over placebo (sham) procedure. Therefore, MSAC considered that because SAD has inferior safety, noninferior effectiveness compared with active conservative management or placebo (sham) procedure, and is more expensive, SAD could not be cost-effective. MSAC considered the equity implications for patients of removing SAD as a standalone procedure from the MBS, including the potential for out-of-pocket costs to increase. However, MSAC decided that continuing to fund SAD as a standalone procedure under the MBS

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<sup>2</sup> Ikonen J, Lähdeoja T, Ardern CL, Buchbinder R, Reito A, Karjalainen T. Persistent Tennis Elbow Symptoms Have Little Prognostic Value: A Systematic Review and Meta-analysis. *Clin Orthop Relat Res.* 2022 Apr 1;480(4):647-660. doi: 10.1097/CORR.0000000000002058. PMID: 34874323; PMCID: PMC8923574.

<sup>3</sup> Hopewell, S., Keene, D. J., Marian, I. R., Dritsaki, M., Heine, P., Cureton, L., Dutton, S. J., Dakin, H., Carr, A., Hamilton, W., Hansen, Z., Jaggi, A., Littlewood, C., Barker, K. L., Gray, A. & Lamb, S. E. 2021. Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. *Lancet*, 398, 416-428.

would be a disservice to patients by exposing them to potential harms for no or little benefit compared with non-surgical therapy. MSAC therefore advised that public subsidy should not continue for medical services for SAD as a standalone procedure on the MBS.

MSAC advised that the department should undergo a consultation process with stakeholders, including patient and consumer representatives, and clinicians who deliver the services, to provide education about MSAC's rationale for recommending delisting of SAD services as a standalone procedure from the MBS. MSAC suggested that a working group of stakeholders could be established to facilitate this process.

## 4. Background

SAD surgery and rotator cuff repair are commonly performed in Australia and are currently reimbursed through a number of MBS items, which include a range of procedures available since 1 December 1991.

The currently subsidised MBS items for SAD (by acromioplasty) are MBS item 48903 and MBS item 48909. Other items related to SAD include 48900 and 48906 (which include excision of the coraco-acromial ligament or removal of calcium deposit) and 48951 and 48960 (which include division of the coraco-acromial ligament, acromioplasty and resection of the acromioclavicular joint).

MSAC has not previously considered items related to SAD.

As part of the Medicare Benefits Schedule (MBS) Review, the final report on the review of Orthopaedic MBS items recommended that for shoulder surgery, existing items for both SAD and rotator cuff repair should be consolidated (recommendation 74, 75)<sup>4</sup>. Subsequently, an additional item has been proposed for larger rotator cuff tears.

In 2020 after considering another application for an intervention for the repair of rotator cuff tear, MSAC recommended that the MSAC Executive review MBS item 48903 for shoulder SAD surgery<sup>5</sup>. During its deliberations of this item, the MSAC Executive noted the results of 2 recent systematic reviews showed that the clinical benefits of these procedures compared to active conservative management was uncertain and advised the department that a full health technology assessment (HTA) review was required prior to the implementation of recommendations 74 and 75.

Terms of reference for this review with subsequent amendments in strikethrough are:

1. Review clinical guidelines on the management of rotator cuff disease, taking account of the clinical characteristics of the population/s recommended for SAD (~~with~~/without rotator cuff repair).
2. Review the utilisation of SAD services, informed by MBS data and other data that may provide additional insight into clinical use.
3. Review evidence on comparative safety and clinical effectiveness of SAD (~~with~~/without rotator cuff repair) used in the management of rotator cuff disease. The evidence review will be based on the population, intervention, comparator and outcomes (PICO) confirmation ratified by the PICO Advisory Sub-committee (PASC).

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<sup>4</sup> <https://www.health.gov.au/resources/publications/taskforce-final-report-orthopaedic-mbs-items>

<sup>5</sup> <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1593-public>

4. Subject to the findings of Terms of reference 1, 2 and 3, review and evaluate the cost effectiveness of SAD (~~with~~/without rotator cuff repair).

Table 1 summarises the advice and direction from MSAC and PASC and how these have been addressed in the DCAR.

**Table 1 Summary of advice and direction from PASC and MSAC**

Component	Matter of concern	How the current assessment report addresses it
The use of subacromial decompression as an adjunct to rotator cuff repair.	As advised by PASC and endorsed by the MSAC Executive, the review of rotator cuff repair was not within the scope of this assessment.	Addressed. The use of subacromial decompression as an adjunct to rotator cuff repair has been removed from the scope of this current review.
The population who may best benefit from SAD is not clearly defined.	PASC requested that the assessment should investigate which prognostic or predictive factors in addition to those defined in the PICO that may further define people who are more likely to benefit from surgery.	Addressed. Sub-group analysis from RCTs and information from observational studies is presented in <a href="#">Section 2</a> and <a href="#">Section 6</a> and used to inform scenario modelling for budget impact. The limitation of this evidence is noted.
The requirement of an economic evaluation.	MSAC considered that an economic analysis should be included as a cost comparison.	Addressed. An economic analysis is included as requested by MSAC (Section 4).
Duration of the condition.	MSAC recognised that trials should be included irrespective of duration of condition.	Addressed. Duration of condition and other treatment effect modifiers is investigated in <a href="#">Section 2.2.4</a> , <a href="#">Section 6.2</a> and Section 6.3. All trials are included irrespective of the duration of symptoms.
Efficacy of specific exercise or physiotherapy interventions.	MSAC noted the limited evidence on the efficacy of exercise physiotherapy or physiotherapy interventions in the management of rotator cuff disease.	Addressed. Recent systematic reviews of conservative therapies for rotator cuff disease are discussed ( <a href="#">Section 1.4.10</a> ). Comment is provided on the natural history of the condition ( <a href="#">Section 1.4.3</a> ).

**Abbreviations**

**MSAC** = Medical Services Advisory Committee; **PASC** = Protocol advisory sub-committee; **PICO** = population, intervention, comparator, outcomes; **RCT** = randomised controlled trial

As part of this review, PASC considered two PICO sets:

- The use of SAD as a standalone procedure (PICO set 1– patients with subacromial impingement)
- The use of SAD in addition to surgery for rotator cuff repair (PICO set 2 – patients for repair of rotator cuff of shoulder).

Following PASC advice and endorsed by the MSAC Executive, the PICO set 2 for the use of SAD as an adjunct to rotator cuff repair was removed from this current assessment. PASC noted that current item numbers (e.g. 48906) are already inclusive of rotator cuff repair with or without SAD. Furthermore, the MBS Review Orthopaedic Clinical Committee Report considered different techniques of SAD including the excision of large bursa, acromioplasty and synovectomy to be

inherent components of rotator cuff repair and should not be co-claimed. A review of rotator cuff repair (with/without SAD) may be endorsed when the results of the Australian Rotator Cuff trial are available (ACTRN12620000789965).

The [final PICO Confirmation](#) is available on the MSAC website<sup>6</sup>.

## 5. Prerequisites to implementation of any funding advice

Services for SAD are currently available through the MBS. There are no prerequisites to any funding advice. Current items for SAD as a standalone item are 48900, 48903 and 48951. Item 48951 is restricted with respect to co-claiming with other surgical services (not being a service associated with any other arthroscopic procedure of the shoulder region). The MBS Review Orthopaedic Clinical Committee Report recommended these items to be consolidated (see Table 2).

Services for SAD used in conjunction with rotator cuff repair are not within the scope of this assessment.

## 6. Proposal for public funding

The Medicare Benefits Schedule (MBS) Review Taskforce Orthopaedics Clinical Committee and the MBS Review Shoulder and Elbow Implementation Liaison Group have proposed the following amended item for SAD performed as any form of open or arthroscopic surgical procedure (MBS 489XX; Table 2).

There is no proposed population. During consultation, SESA recommended that patient selection for acromioplasty should be:

- A failure of nonoperative measures over 4–6 months
- Examination consistent with impingement and with the exclusion of other common causes of shoulder pain such as adhesive capsulitis, long head of biceps tendonitis, osteoarthritis etc.
- Ongoing untenable symptoms
- The demonstration of a mechanical cause for the cuff impingement (e.g. radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion)

The intervention is a mix of procedures, based on patient presentation and shoulder anatomy. As per the ratified PICO confirmation, the use of SAD in conjunction with rotator cuff tear repair is not a part of this assessment of SAD as a standalone procedure. As the fees for the proposed amended MBS item have yet to be determined, the out-of-pocket costs are uncertain.

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<sup>6</sup> <https://www1.health.gov.au/internet/msac/publishing.nsf/Content/1711-public>

**Table 2 Proposed amended MBS item for SAD**

<b>Category 3 – Therapeutic Procedures Group T8 – Surgical Operations Subgroup 15 – Orthopaedic Subheading 8 – Shoulder</b>
MBS 489XX Open or arthroscopic subacromial decompression of Shoulder Inclusive of, if performed: i) coraco-acromial ligament division ii) acromioplasty iii) excision of outer clavicle and acromioclavicular joint iv) removal of calcium deposit v) excision of bursa Not being a service associated with a service to which any open or arthroscopic shoulder region procedure applies. (Anaes.) (Assist.)
Fee: Not provided

**Abbreviations**

**MBS** = Medical Benefits Schedule

**Source**

Page 24 of the [Ratified PICO confirmation](#)

## **7. Population**

As identified in the Ratified PICO Confirmation, the population is adult patients with symptomatic subacromial shoulder impingement (PICO set 1) and symptoms unresolved despite active conservative therapy for 6 months.

Subacromial shoulder impingement is diagnosed with a range of physical tests, and also with the use of imaging, such as X-ray, to exclude other pathologies of the shoulder (as per PICO).

SAD is considered for patients who have ongoing pain and/or shoulder dysfunction following a course of active conservative therapy.

## **8. Comparator**

The comparator as identified in the Ratified PICO Confirmation is continued active conservative therapy, including physiotherapy, exercise therapy, movement therapy, medications for pain and inflammation, as well as subacromial injections of corticosteroid or local anaesthetic. The assessment has also included placebo<sup>7</sup> (diagnostic arthroscopy) as an additional comparator, as reflected in a small number of published trials.

Although all clinical guidelines recommend active conservative therapy for all rotator cuff-related pain, there is no defined protocol. In practice, it is likely that patients receive care tailored to their own experience and their ability to access different services and advice, which may include GPs, physiotherapists, rheumatologists, radiologists, and surgeons.

A musculoskeletal condition that has been present or is likely to be present for 6 months or longer is termed a chronic medical condition, and patients are eligible to have a chronic disease

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<sup>7</sup> Standard medical management (reflected in studies as no treatment, placebo or sham treatment) may include the use of medicines, medical services, best supportive care or conservative management; [Guidelines for preparing assessments for MSAC, p36](#)



management (CDM) plan, formerly enhanced primary care (EPC), through the MBS and prepared by their general practitioner (GP). CDM will enable the GP to plan and coordinate a multidisciplinary team, which may include physiotherapy. Under the CDM, the patient is allocated up to 5 sessions with a Medicare rebate for allied health services in a calendar year, which includes physiotherapy (MBS 10960 or 10953). The patient is required to pay any gap fee for these 5 sessions<sup>8</sup>. Without the CDM plan, the full physiotherapy cost is paid by the patient. Private health insurance can cover a portion of the cost of any continued or additional services subject to yearly cost limits and level of coverage. Patients can only claim one source of payment for each service (that is either MBS or private health insurance).

For ultrasound (US)-guided subacromial injections, there are two MBS items available (55848, 55850). An additional MBS item is available for US-guided injections in combination with a diagnostic musculoskeletal US service (55850).

## 9. Summary of public consultation input

Consultation feedback previously provided on this assessment is summarised in full in the [PICO Consultation](#) and [Clinical Guidelines Review](#), available on the MSAC website.

Consultation input was received from two (2) professional organisations and two (2) individuals, both health professionals. The organisations were:

- Shoulder and Elbow Society of Australia (SESA)
- Australian Physiotherapy Association (APA)

The SESA noted that subacromial decompression may be warranted for extrinsic causes of compression and provided either standalone or with the repair of a rotator cuff tear. Standalone subacromial decompression can be used where there is no loss of rotator cuff function. Arthroscopic acromioplasty can reduce the risk of rotator cuff disease in the future. However, acromioplasty should not be used for shoulder pain alone.

The APA noted that assessment of patients, including findings from X-ray assessment could be used to determine a mechanical cause of impingement. Target structures should be identified prior to surgery. The APA also agreed with the proposed eligibility criteria, including exclusion of instability, to have included a course of physiotherapy over at least 4-6 months, demonstrate a mechanical cause for cuff impingement, exclude other common causes of shoulder pain, chronic pain or central sensitisation.

The APA noted guidelines for best practice are unclear and best practice care is not always financially accessible for patients.

One health professional provided a recent Australian article discussing a lack of benefit of number of surgical interventions compared to placebo surgery, including arthroscopy for shoulder pain<sup>9</sup>.

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<sup>8</sup> Australian Government - Department of Health. 2021. *MBS Online Medicare Benefits Schedule - Item 10960* [Online]. Available: <http://www9.health.gov.au/mbs/fullDisplay.cfm?q=10960&qt=ItemID&type=item> [Accessed 3 February 2022]

<sup>9</sup> Ferreira G, Harris I, Zadro J and O'Keefe M. 2022. 3 orthopaedic surgeries that might be doing patients (and their pockets) more harm than good [Online]. *The Conversation*.

## 10. Characteristics of the evidence base

Broadly speaking the evidence base and this report aligns with the final PICO. Any variations, uncertainties, and applicability to the Australian context, particularly regarding the population, is described.

The evidence base presented is similar to that used in a recent Cochrane review<sup>10</sup>. Any differences are noted, with comments provided.

### Overall quality of studies

A total of 17 studies (inclusive of 9 randomised controlled trials [RCTs] reported in 9 publications and 5 case series studies) met the inclusion criteria for assessing the safety and effectiveness of SAD compared to active conservative therapy. The RCTs had a total number of 1,179 randomised participants. Two follow-up publications of the FIMPACT trial and one new RCT are available in addition to those in the Cochrane review<sup>11</sup>. Due to the lack of reporting of safety data in the RCTs, 5 case series with populations greater than 1,000 were used for safety outcomes but not for effectiveness.

Due to multiple publications, each trial is referred to by the surname of the first author (e.g. Beard) (see also Table 3).

Two trials at low risk of bias included the use of sham surgery as a placebo (Beard, Paavola).

Other trials were at higher risk of bias, commonly due to a lack of protocol, a lack of information regarding randomisation, an inability to blind across treatment populations, and imbalances across reported populations at follow-up. The GRADE certainty of evidence was moderate to high for comparisons to placebo (sham) procedure, and low or very low for comparisons with active conservative therapy.

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<sup>10</sup> Karjalainen TV, Jain NB, Page CM, Lahdeoja TA, Johnston RV, Salamh P, Kavaja L, Ardern CL, Agarwal A, Vandvik PO and Buchbinder R 2019b. Subacromial decompression surgery for rotator cuff disease. *Cochrane Database of Systematic Reviews*, 1, CD005619.

<sup>11</sup> Bäck M, Paavola M, Aronen P, Järvinen TLN and Taimela S 2021. Return to work after subacromial decompression, diagnostic arthroscopy, or exercise therapy for shoulder impingement: a randomised, placebo-surgery controlled FIMPACT clinical trial with five-year follow-up. *BMC musculoskeletal disorders*, 22, 889.

Cederqvist S, Flinckila T, Sormaala M, Ylinen J, Kautiainen H, Irmola T, Lehtokangas H, Liukkonen J, Pamilo K, Ridanpaa T et al. 2021. Non-surgical and surgical treatments for rotator cuff disease: A pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation. *Annals of the Rheumatic Diseases*, 80, 796-802.

Paavola M, Kanto K, Ranstam J, Malmivaara A, Inkinen J, Kalske J, Savolainen V, Sinisaari I, Taimela S and Järvinen TL 2021. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: a 5-year follow-up of a randomised, placebo surgery controlled clinical trial. *British journal of sports medicine*, 55, 99-107.

**Table 3 Key features of the included evidence comparing SAD with active conservative therapy or placebo**

<b>Trials</b>	<b>N</b>	<b>Design/duration</b>	<b>Risk of bias</b>	<b>Patient population</b>	<b>Outcome(s)</b>	<b>Use in modelled evaluation</b>
SAD vs active conservative treatment						
Beard (Beard et al., 2015, Beard et al., 2018)	313 (106 decompression surgery; 103 arthroscopy only; 104 no treatment)	Multicentre, randomised, pragmatic, parallel group, placebo-controlled, 3-group trial  1-year follow-up	Low	Patient with subacromial pain for at least 3 months with intact rotator cuff tendons	Pain Shoulder function	No*
Brox (Brox et al., 1999, Brox et al., 1993)	125 (45 arthroscopic surgery; 30 placebo laser; 50 supervised exercise)	Randomised clinical trial  2.5-year follow-up	High	Rotator cuff disease (stage II impingement syndrome)	Pain Shoulder function	No*
Cederqvist (Cederqvist et al., 2021)	417 (190 surgical; 190 non-surgical)	Pragmatic randomised clinical trial  2-year follow-up	Some concerns	Patients with long-term (>3 months) subacromial pain	Pain Shoulder function	No*
Farfaras (Farfaras et al., 2016, Farfaras et al., 2018)	87 (15 open surgery; 29 arthroscopic surgery; 34 nonoperative treatment)	Prospective randomised study  2 to 3 years after the intervention	High	SAIS	Shoulder function Quality of life	No*
Haahr (Haahr and Andersen, 2006, Haahr et al., 2005)	84 (41 arthroscopic surgery; 43 physiotherapy)	Randomised controlled study  1-year follow-up	Some concerns	Subacromial impingement	Pain and dysfunction score Shoulder function	No*
Ketola (Ketola et al., 2009, Ketola et al., 2016, Ketola et al., 2015, Ketola et al., 2017)	140 (70 exercise; 70 acromioplasty with exercise)	Randomised controlled trial  1-year follow-up	Some concerns	Stage II SAIS	Pain	No*
Paavola (Bäck et al., 2021, Paavola et al., 2021, Paavola et al., 2018, Paavola et al., 2017)	210 (139 surgery [SAD or diagnostic arthroscopy]; 71 exercise therapy)	Multicentre, 3-group, randomised, double-blind, sham-controlled trial.	Low	Patients with symptoms associated with shoulder impingement syndrome	Effectiveness: Pain Shoulder function	No*

<b>Trials</b>	<b>N</b>	<b>Design/duration</b>	<b>Risk of bias</b>	<b>Patient population</b>	<b>Outcome(s)</b>	<b>Use in modelled evaluation</b>
		2-year follow-up			Return to work  Safety: Complication and adverse events	
Peters (Peters and Kohn, 1997)	72 (32 surgery; 40 nonoperative treatment)	Prospective randomised study  4-year follow-up	High	SAIS	Pain Mobility Instability Activity Overhead work	No*
Rahme (Rahme et al., 1998)	42 (number per group not specified at baseline)	Randomised prospective study  1-year follow-up	High	SAIS	Pain	No*
<b>SAD versus placebo (sham) procedure</b>						
Beard (Beard et al., 2015, Beard et al., 2018)	313 (106 decompression surgery; 103 arthroscopy only; 104 no treatment)	Multicentre, randomised, pragmatic, parallel group, placebo-controlled, 3-group trial  1-year follow-up  Placebo is arthroscopy	Low	Patient with subacromial pain for at least 3 months with intact rotator cuff tendons	Pain Shoulder function	No*
Brox (Brox et al., 1999, Brox et al., 1993)	125 (45 arthroscopic surgery; 30 placebo laser; 50 supervised exercise)	Randomised clinical trial  2.5-year follow-up  Placebo is detuned laser	High	Rotator cuff disease (stage II impingement syndrome)	Pain Shoulder function	No*
Paavola (Bäck et al., 2021, Paavola et al., 2021, Paavola et al., 2018, Paavola et al., 2017)	210 (139 surgery [SAD or diagnostic arthroscopy]; 71 exercise therapy)	Multicentre, 3-group, randomised, double-blind, sham-controlled trial.	Low	Patients with symptoms associated with shoulder impingement syndrome	Effectiveness: Pain Shoulder function	No*

<b>Trials</b>	<b>N</b>	<b>Design/duration</b>	<b>Risk of bias</b>	<b>Patient population</b>	<b>Outcome(s)</b>	<b>Use in modelled evaluation</b>
		2-year follow-up  Placebo is arthroscopy			Return to work  Safety: Complication and adverse events	
Shoulder arthroscopic surgery						
Shields (Shields et al., 2015)	10,570	Prognostic case series 30 days	Moderate	Shoulder arthroscopy cases from the adult American College of Surgeons NSQIP database from 2005 and 2011	Complications 30-day mortality 30-day morbidity (major and minor complications)	No*
Heyer (Heyer et al., 2020)	134,822	Case series 30 days	Moderate	Shoulder and knee arthroscopy, including shoulder arthroscopy with SAD from the adult American College of Surgeons NSQIP database from 2010 and 2016	30-day complications and mortality	No*
Hill (Hill et al., 2017)	15,385	Prognostic case series 30 days	Moderate	Shoulder arthroscopy cases from the adult American College of Surgeons NSQIP database from 2011 and 2013	30-day readmission  Complications (major and minor complications)	No*
Rees (Rees et al., 2022)	261,248	Case series 90 days	Moderate	Shoulder arthroscopy cases from the Hospital	Death, reoperation or adverse event within 90 days	No*

<b>Trials</b>	<b>N</b>	<b>Design/duration</b>	<b>Risk of bias</b>	<b>Patient population</b>	<b>Outcome(s)</b>	<b>Use in modelled evaluation</b>
				Episode Statistics for NHS England database from 1 April 2009 to 31 March 2017	Reoperation within 1 year	
Yeranosian (Yeranosian et al., 2014)	165,820 (consecutive, from a database)	Case series 30 days	Very high	Shoulder arthroscopy  Cases from a United States insurance database between 2004 and 2009.	Infections and reoperations within 30 days	No*

#### **Abbreviations**

**N** = number, **NSQIP** = National Surgical Quality Improvement Program, **SAD** = subacromial decompression, **SAIS** = subacromial impingement syndrome.

#### **Note**

\* = a modelled economic evaluation was not undertaken for this assessment.

Where reported, patients within studies appeared well matched at baseline between study groups.

Across the duration of the trials, relatively large proportions of patients had interventions other than that to which they were randomised or did not receive the intervention per protocol. Of the patients who were allocated to active conservative therapy, between 10% (Farfaras) and 57% (Rahme) converted to surgery. Where permitted, these changes in intervention would suggest a lack of subjective patient satisfaction.

Relevant outcomes, in line with the ratified PICO confirmation, were reported by all studies. Where reported, there were no differences in results between intention-to-treat (ITT) and per-protocol analyses (Beard, Ketola, Paavola).

### **Population characteristics**

Broadly, patients in all trials were similar, and selected on the basis of subacromial pain or impingement, with similar mean ages of between 44 and 59 years representing a relatively young population of working age. Patients in the RCTs had symptoms for at least 3 months, with durations of about 1 year (where reported). Other shoulder pathologies commonly included were full-thickness rotator cuff tears (FTT), osteoarthritis (of the glenohumeral or acromioclavicular joint), rheumatoid arthritis, instability, adhesive capsulitis, calcific tendinitis and trauma. Cederqvist included treatment for tenotomy of the long head of the biceps as part of the intervention, although the use of this procedure is not reported. Cederqvist and Rahme did not exclude FTT.

In one trial, the diagnosis was left to local protocols (Beard). The results may therefore be reflective of patient selection in the UK, but the applicability to Australian clinical practice is uncertain. Physical tests were used in all trials. Imaging, such as X-ray, were commonly used to exclude other shoulder pathologies, and a positive impingement test (injection of local anaesthetic to the subacromial space) was also used. In two studies the use of imaging was

unclear, or imaging was not used (Beard, Brox). The use of imaging to confirm the cause of impingement, or the pathology of the identified impingement was not commonly described.

In Cederqvist, all patients underwent a 3-month formal rehabilitation program (with a recommended 15 physiotherapy sessions) prior to randomisation to surgery, or continuation of rehabilitation. 39 per cent (161/417) of participants were subsequently excluded from further participation due to a combination of improved symptoms and change of diagnosis. This study is therefore likely to reflect best practice most closely, in line with the PASC-approved PICO, although outcome data were not available solely for patients treated with SAD.

One trial reported the presence of impingement in between 61% and 75% of patients who underwent surgery (Beard). This may reflect a lack of precision in patient selection, either for this study or in clinical practice as a whole.

In all trials, patients were required to have failed active conservative therapies although the duration and type of therapy is rarely reported. Therefore, it is unlikely that all patients underwent a formal rehabilitation program for 6 months and may not align with the population described in the PICO Confirmation.

Baseline characteristics of pain and function varied between studies from better to worse scores. Better scores for pain did not always coincide with better scores for function. This may indicate variability across trials in terms of the severity of the shoulder pathology. The impact on outcomes is unclear.

No trial used a predefined threshold of pain, shoulder function or size of tear as criteria for selection. As a result, patients are likely to be included regardless of whether their presentation had been determined to reach a certain level of clinical severity.

## **Intervention and comparator**

Interventions are similar across trials, commonly including use of bursectomy, release of the coraco-acromial ligament and removal of a subacromial bone spur. Removal of calcium deposits or resection of the lateral end of the clavicle are not mentioned as part of the surgical interventions. Studies do not report any variation in the procedures, or if there were changes to the intervention based on the shoulder anatomy, although Ketola describes the releasing of the coraco-acromial ligament only if it felt tight or thick.

All patients included standard postoperative rehabilitation, which commonly involved one or more physiotherapy visits and guidance for home exercises.

Ongoing or additional active conservative co-interventions such as pain medications, anti-inflammatories and subacromial injections of corticosteroids were not described in all trials, and therefore their use is uncertain.

Across all trials, 4 distinct comparators were reported.

The most common comparator was exercise therapy. In many cases, the therapy was for 3–6 months, with supervision (1-hour session, 1–3 times per week where reported) gradually reduced over time as patients became familiar with the exercises (Brox, Farfaras, Paavola). Physiotherapy by the method of Bohmer was mentioned by 2 trials (Farfaras, Rahme).

A sham surgery placebo was reported in 2 trials (Beard, Paavola). Placebo was arthroscopy only, with exactly the same approach as SAD but with no surgical removal or excision (Beard). In Paavola, bursal tissue could be stretched or resected, keeping resection to a minimum. In both trials, postoperative rehabilitation was the same as for the SAD group.

One trial used active monitoring with specialist reassessment (Beard). Patients attended a reassessment appointment 3 months after entering the study.

One trial used a placebo therapy of a detuned laser given in 12 sessions, with no additional physiotherapy or exercise therapy (Brox). However, after a preliminary analysis of outcomes showed inferior results, the laser therapy was discontinued after 6 months. Most patients originally randomised to laser therapy received SAD (15 received SAD and 2 had a different treatment from a total cohort of 30).

## **11. Comparative safety**

### **Adverse events and complications**

Across all included studies, reported adverse events were in line with the outcomes provided in the PICO Confirmation, noting that there was no reported incidence of wasting or avulsion of the deltoid muscle.

Adverse events are rarely reported in the RCTs. Table 4 presents the reported adverse events and complications based on 2 RCTs (Beard, Paavola) and 5 large case series studies from the US and UK (Shields, Heyer, Hill, Rees, Yeranosian). Case series reported outcomes at 30 days (Heyer, Hill, Shields, Yeranosian) or 90 days and 1 year (Rees).

Due to the low event rate reported in the 2 RCTs (Beard, Paavola), the reported adverse events were pooled for placebo (sham) procedure and active conservative management interventions and compared to SAD. An adverse event was reported in 1.9% to 5.1% of the patients who had SAD and 1.4% to 2.8% of patients with active conservative therapy or placebo (sham) procedure. Frozen shoulder was the most commonly-reported event; studies do not describe how this was resolved.

The included case series reported 30-day major and minor complications, or reoperations for infections (open or closed surgical drainage) associated with shoulder arthroscopy (Hill, Shields, Yeranosian). However, the population was from a database not restricted to shoulder decompression surgery and included procedures such as rotator cuff repair, superior labrum anterior and posterior (SLAP) lesion repair, capsulorrhaphy, distal claviclectomy, extensive debridement, limited debridement, lysis and resection of adhesions with or without manipulation, biceps tenodesis, complete synovectomy, foreign-body removal and partial synovectomy. These interventions represent a broader range of arthroscopic procedures and may reflect a slightly more invasive set of operations. The reported rates for mortality and major and minor complications were 1.00% to 1.17% of the patients who had shoulder arthroscopy. Heyer reported safety outcomes from the same database for SAD, with an overall complication rate (including death) of 0.65%.



**Table 4 Safety outcomes**

Study types and outcomes	Intervention	Comparator
Randomised controlled trials		
Frozen shoulder	<ul style="list-style-type: none"> <li>1.9% (2/106) Beard</li> <li>5.1% (3/59) Paavola</li> </ul>	Conservative therapy <ul style="list-style-type: none"> <li>1.9% (2/104) Beard</li> <li>2.8% (2/71) Paavola</li> </ul> Placebo <ul style="list-style-type: none"> <li>1.9% (2/103) Beard</li> <li>1.6% (1/63) Paavola</li> </ul>
Low back pain		Conservative therapy <ul style="list-style-type: none"> <li>1.4% (1/71) Paavola</li> </ul>
Temporary swelling postoperative		Placebo <ul style="list-style-type: none"> <li>1.6% (1/63) Paavola</li> </ul>
Overall adverse event rate (p = 0.86)	<ul style="list-style-type: none"> <li>3.0% (5/165) Beard, Paavola</li> </ul>	<ul style="list-style-type: none"> <li>3.7% (9/241) Beard, Paavola</li> </ul>
Case series		
Overall adverse event rate: <b>Arthroscopic shoulder surgery</b>	<ul style="list-style-type: none"> <li>1.17% (175/15,015) Hill</li> <li>1.0% (103/10,255) Shields</li> <li>0.27% (450/165,820) Yeranosian (reoperations for surgical drainage)</li> </ul>	
Overall adverse event rate: <b>Subacromial decompression</b>	<ul style="list-style-type: none"> <li>0.65% (210/32,228) Heyer</li> <li>1.15% (1,186/103,211) Rees</li> </ul>	

From a prospective insurance database of 165,820 patients in the United States, there was an overall infection rate (represented by reoperations within 30 days for surgical drainage) of 0.27% (450/165,820) following shoulder arthroscopy (Yeranosian).

A recently published dataset from the UK of 103,211 patients showed an overall rate of adverse events or reoperation within 90 days following SAD of 1.15% (95% confidence interval 1.09 to 1.22) (Rees).

Evidence from published systematic review state that active conservative therapies are safe, with reported adverse events transient and mild.

## 12. Comparative effectiveness

All clinical effectiveness outcomes requested in the PICO Confirmation were available.

The assessment for effectiveness is limited by the low quality of evidence based on the GRADE quality appraisal on outcomes such as pain, shoulder function, HRQoL and return to work in comparing SAD with active conservative therapy.

### Pain

Based on the available data from the included RCTs, pain scores at different timepoints were generally lower for patients who had SAD compared to active conservative therapy or placebo (sham) procedure (Table 5).

When compared to active conservative therapy, the mean difference in pain score was not statistically significant except at the 3-month timepoint. However, the difference in pain level was not clinically relevant based on a minimum clinically important difference (MCID) of 1.5 points. There was no difference in pain for SAD compared with placebo (sham) procedure.

**Table 5 Pooled data from RCTs, mean difference between groups (SAD and active conservative therapy/placebo) at follow-up for pain**

Timepoints	SAD vs conservative therapy (mean [95% confidence interval])	SAD vs placebo (mean [95% confidence interval])
3 months	<b>-0.68 (-1.32 to -0.03) (p = 0.04)</b>	0.50 (-0.41 to 1.41)
6 months	-0.48 (-1.00 to 0.04)	-1.01 (-3.24 to 1.21)
1 year	-0.77 (-1.59 to 0.04)	-0.27 (-0.85 to 0.31)
2 years	-0.35 (-1.34 to 0.64)	-0.90 (-1.80 to 0.00)
5 years	-0.12 (-0.57 to 0.33)	-0.80 (-1.71 to 0.11)
10 years	1.0 (-0.24 to 2.24)	NR

**Abbreviations**

NR = not reported, SAD = subacromial decompression.

**Notes**

Pain (0–10); lower scores mean less pain. Minimal clinically important difference = 1.5 points

p > 0.05 unless otherwise shown

Bold text indicates statistically significant results

**Source**

Figure 6, Figure 10

## Shoulder function

**Table 6 Pooled data from RCTs, mean difference between groups (SAD and active conservative therapy/placebo) at follow-up for shoulder function**

Timepoints	SAD vs conservative therapy (mean [95% confidence interval])	SAD vs placebo
3 months	6.21 (-7.34 to 19.76)	NR
6 months	2.71 (-4.67 to 10.09)	-0.70 (-6.33 to 4.93)
1 year	3.60 (-9.16 to 16.37)	1.30 (-4.53 to 7.13)
2 years	5.91 (2.08 to 9.74)	4.20 (-1.72 to 10.12)
5 years	4.41 (-1.71 to 10.53)	<b>7 (0.75 to 13.25) (p = 0.03)</b>
10 years	<b>9.59 (1.98 to 17.19) (p = 0.01)</b>	NR

**Abbreviations**

NR = not reported, SAD = subacromial decompression.

**Notes**

Function (0–100); higher scores mean better function: MCID = 8.3 points

p values are greater than 0.05 unless otherwise shown

Bold text indicated statistically significant results

**Source**

Figure 7, Figure 11

Table 6 shows the mean difference in shoulder function scores at different timepoints between SAD and active conservative therapy/placebo. For surgery versus active conservative therapy, while a higher shoulder function score was evident at all timepoints, this difference was not statistically significant) except at the 10-year follow-up timepoint. The mean difference between SAD and active conservative therapy at the 10-year follow-up timepoint was statistically

significant and clinically important based on the MCID for shoulder function of 8.3 points. Based on GRADE, there is a very low certainty of evidence regarding SAD’s impact on shoulder function.

SAD showed a higher shoulder function score compared to placebo (sham) procedure, although the results were not statistically significant for most reported timepoints and were not clinically important. The result comparing surgery and placebo was of high certainty.

### Health-related quality of life (HRQoL)

The HRQoL was not significantly different at all timepoints when comparing SAD with active conservative therapy (3 RCTs) or placebo (2 RCTs). Therefore, SAD has little to no effect on HRQoL. The result may be influenced by the low number of studies included in the review and the low certainty on the quality of evidence for SAD vs active conservative therapy and high certainty for SAD vs placebo (sham) procedure.

### Return to work

The number of patients who were able to return to work at different timepoints is presented in Table 7. Compared to active conservative therapy, the percentage of patients who returned to work after surgery is not statistically different. However, the evidence on the effect of SAD vs active conservative therapy on patients’ return-to-work status or ability is uncertain due to the very low level of certainty on the quality of the studies included in the review. Only one RCT was available to compare SAD with placebo (sham) procedure, with moderate level of evidence certainty based on GRADE.

**Table 7 Pooled data from RCTs, percentage of patients who returned to work at different timepoints**

Timepoints	SAD vs conservative therapy (% [n/N])	SAD vs placebo (% [n/N])
3 months	SAD: 66% (39/59) CT:69% (47/68)	NR
6 months	SAD: 77% (67/87) CT: 73% (73/100)	NR
1 year	SAD: 86% (48/56) CT: 87% (55/63)	NR
2 years	SAD: 74% (65/88) CT: 78% (79/101)	SAD: 82% (47/57) P: 80% (47/59)
5 years	SAD: 66% (110/153) CT: 67% (107/160)	SAD: 67% (38/57) P: 69% (41/59)
10 years	SAD: 98% (43/44) CT: 91% (42/46)	NR

#### Abbreviations

CT = conservative therapy, NR = not reported, P = placebo, SAD = subacromial decompression surgery.

#### Source

Figure 9, Section 2.2.3

### Failure of surgery and reoperations

Compared with active conservative therapy, the presence of full-thickness tears as identified with MRI was similar at 5 years (1 study) and improved for patients following SAD at 13 years (1 study).

Additional surgery or reoperation was not commonly reported. One trial reported a total of 4 reoperations (1/59 for SAD, 3/15 for patients who converted to SAD from active conservative therapy) including additional SAD, distal clavicle resection, and long head of biceps repair (Paavola). There were no other reported reoperations, and none in patients treated with diagnostic arthroscopy.

## GRADE quality assessment

The summary of findings for the GRADE quality assessment is shown in Table 8 and Table 9.

Depending on the reported outcome, the number of RCTs available for the comparison with active conservative therapy varied. Accordingly, the certainty of evidence varied from moderate to very low based on the number and risk of bias of the RCTs. At 12 months there were no statistically significant differences reported for pain (low certainty evidence), HRQoL (low certainty evidence) and return to work (very low certainty evidence). The main reason the evidence was downgraded was due to the risk of detection and performance bias, as participants were not blinded to their treatment allocations. Moderate-certainty evidence shows no statistically significant difference reported on the total adverse events. However, the certainty of evidence was downgraded due to imprecision and the low event rates reported.

**Table 8 Clinical benefit and harm using SAD versus active conservative therapy**

Outcome (units) Follow-up	Participants (studies)	Quality of evidence	Risk of bias	Range of effect
Pain (12 months)	316 participants (k=3)	⊕⊕○○ Low	Serious	0.77 points lower to 1 point higher
Shoulder function (12 months)	259 participants (k=3)	⊕○○○ Very low	Serious	2.71 to 9.59 points higher
HRQoL (12 months)	116 participants (k=1)	⊕⊕○○ Low	Serious	Not estimable
Return to work (5 years)	313 participants (k=3)	⊕○○○ Very low	Serious	27 fewer to 167 more people
Total adverse events (12–24 months)	406 participants (k=2)	⊕⊕⊕○ Moderate	Serious	26 fewer to 62 more people

### Abbreviations

HRQoL = health-related quality of life, SAD = subacromial decompression surgery.

### Source

Table 63

**Table 9 Clinical benefit and harm of using SAD versus placebo (sham) procedure**

Outcome (units) Follow-up	Participants (studies)	Quality of evidence	Risk of bias	Range of effect
Pain	281 participants (k=2)	⊕⊕⊕⊕ High	Not serious	0.85 points lower to 0.31 points higher
Shoulder function	157 participants (k=1)	⊕⊕⊕⊕ High	Not serious	4.57 points lower to 7.13 points higher
HRQoL	285 participants (k=2)	⊕⊕⊕⊕ High	Not serious	0.28 points lower to 0.18 points higher
Return to work	116 participants (k=1)	⊕⊕⊕○ Moderate	Serious	100 fewer to 183 more people

**Abbreviations**

**HRQoL** = health-related quality of life, **SAD** = subacromial decompression surgery.

**Source**

Table 64

High-certainty evidence indicates that SAD compared to placebo (sham) procedure provides no improvement in pain, shoulder function or HRQoL. There is no statistically significant difference reported in the return-to-work outcome between SAD and placebo (sham) procedure based on moderate-certainty evidence.

The certainty of evidence was moderate to high due to the inclusion of 2 RCTs at low risk of bias.

**Overall clinical claim**

This review is not based on a formal application with a defined clinical claim. However, based on the benefits and harms reported in the evidence base, data synthesis showed that there was no difference in the use of SAD versus active conservative therapy on clinical effectiveness outcomes such as pain, shoulder function, HRQoL and return to work, and on clinical safety outcome (total adverse events). For shoulder function, compared with active conservative therapy, surgery reaches clinical significance at the 10-year timepoint, with a mean difference in shoulder function scores of 9.59 (95% confidence interval [CI] 1.98 to 17.19). However, this is based on results from 2 trials of very low certainty and so should be treated with caution.

SAD does not show statistically and clinically significant difference on outcomes such as pain, shoulder function, HRQoL and return to work compared to placebo (sham) procedure based on moderate to high certainty of evidence.

Reported adverse events associated with SAD, active conservative therapy and placebo (sham) procedure were rare. Case series evidence shows that serious adverse events associated with subacromial decompression are not common. Systematic reviews have found that adverse events associated with active conservative therapies are mild and transient.

The trial populations likely reflect a broader population of patients who were not selected based on defined criteria of pain or function, and previous active conservative therapies varied. Due to the lack of defined populations in the current and proposed MBS items the applicability of this evidence to Australian practice is uncertain.

**13. Economic evaluation**

Based on MSAC advice, a cost comparison analysis was undertaken to compare SAD with active conservative therapy. The cost comparison was based on the framework of a cost-minimisation

analysis (CMA). However, as clinical non-inferiority was not established this analysis should not be considered a CMA study. The cost comparison takes an expanded Australian health system perspective, where some of the costs payable by patients and private insurers are also included. The inclusion of these service costs ensured the completeness of the service delivery.

Various costs and levels of service utilisations were incorporated in the cost analysis. The information was sourced from MBS statistics, published literature and available clinical practice guidelines. This information was also used to inform assumptions regarding plausible clinical situations. Due to the high levels of uncertainty for service use in the evidence base and in Australian clinical practice, the result of the cost comparison is likely to be highly uncertain. One-way deterministic sensitivity analyses and scenario analyses were performed to investigate the cost drivers of the uncertainties. A summary of the assumptions used in each scenario is shown in Table 10. Key analysis results are summarised in Table 11.

**Table 10 Assumptions and parametric uncertainties involved in cost comparison calculations**

Service item	Base-case value <sup>a</sup>	Uncertainty ranges	Usage of the assumption in scenarios	Assumption references
MBS 10960 (Physiotherapy)	20%	12.6%, 80.5%	Scenario 1, 2	Literature <sup>b</sup>
MBS 10953 (Exercise physiology)	20%	12.6%, 80.5%	Scenario 1, 2	Literature <sup>b</sup>
MBS 721 (GP management plan)	20%	12.6%, 80.5%	Scenario 1, 2	Literature <sup>b</sup>
MBS 723 (GP coordinate team care arrangements)	20%	12.6%, 80.5%	Scenario 1, 2	Literature <sup>b</sup>
MBS 63325 (MRI of shoulder)	43.3%	0.5%, 72%, 0%	Scenario 1, 2, 3	Literature <sup>b</sup> , clinical guidelines
MBS 56627 (CT of shoulder)	4.4%	0.2%, 0%	Scenario 1, 3	Literature <sup>c</sup> , clinical guidelines
MBS 55864 (US of shoulder, unilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature <sup>b</sup>
MBS 55865 (US of shoulder, unilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature <sup>b</sup>
MBS 55866 (US of shoulder, bilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature <sup>b</sup>
MBS 55867 (US of shoulder, bilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature <sup>b</sup>
MBS 57700 (X-ray of shoulder)	51%	19%, 46.8%	Scenario 1, 2	Literature <sup>b</sup>
MBS 57703 (X-ray of shoulder)	51%	19%, 46.8%	Scenario 1, 2	Literature <sup>b</sup>
Specialist physiotherapy <sup>f</sup>	6	2, 12	Scenario 1, 2	Literature <sup>d</sup> , clinical guidelines
Post-surgery rehabilitation	2	1, 4	Scenario 1, 2	Literature <sup>e</sup>

**Abbreviations**

MBS = Medicare Benefit Schedule.

**Note**

Scenario 1 assumptions were based on an overall lower rate of physiotherapy and diagnostic imaging as identified in the literature  
 Scenario 2 assumptions were based on an overall higher rate of physiotherapy and diagnostic imaging services as identified in the literature

Scenario 3 involves the exclusion of MRI and CT from active conservative therapy in line with guidelines that do not recommend these services to be available in primary care

**a** = The base-case assumptions were taken from utilisation data for item 48951, other than for specialist physiotherapy and post-surgery rehabilitation

**b** = Naunton, J., Harrison, C., Britt, H., Haines, T. & Malliaras, P. 2020. General practice management of rotator cuff related shoulder pain: A reliance on ultrasound and injection guided care. *PLoS One*, 15, e0227688-e0227688.

Smythe, A., Rath, S., Pavlova, N., Littlewood, C., Connell, D., Haines, T. & Malliaras, P. 2021. Self-reported management among people with rotator cuff related shoulder pain: An observational study. *Musculoskelet Sci Pract*, 51, 102305.

**c** = Naunton, J., Harrison, C., Britt, H., Haines, T. & Malliaras, P. 2020. General practice management of rotator cuff related shoulder pain: A reliance on ultrasound and injection guided care. *PLoS One*, 15, e0227688-e0227688.

**d** = Hopewell, S., Keene, D. J., Marian, I. R., Dritsaki, M., Heine, P., Cureton, L., Dutton, S. J., Dakin, H., Carr, A., Hamilton, W., Hansen, Z., Jaggi, A., Littlewood, C., Barker, K. L., Gray, A. & Lamb, S. E. 2021. Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. *Lancet*, 398, 416-428.

**e** = Beard, D. J., Rees, J. L., Cook, J. A., Rombach, I., Cooper, C., Merritt, N., Shirkey, B. A., Donovan, J. L., Gwilym, S., Savulescu, J. & Et Al. 2018. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. *Lancet (london, england)*, 391, 329 - 338.

Cederqvist, S., Flinkkila, T., Sormaala, M., Ylinen, J., Kautiainen, H., Irmola, T., Lehtokangas, H., Liukkonen, J., Pamilo, K., Ridanpaa, T. & Et Al. 2021. Non-surgical and surgical treatments for rotator cuff disease: A pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation. *Annals of the Rheumatic Diseases*, 80, 796 - 802.

**f** = Specialist physiotherapy is provided by an experienced physiotherapist as the alternative to surgery after the patient has exhausted the physiotherapy sessions available through the MBS chronic disease management plan

**Table 11 Cost comparison results between SAD with and without surgery**

Scenario	Key driver in the scenario analysis	Intervention with SAD surgery	Intervention without SAD surgery	Cost difference
Base-case		\$6,474	\$1,239	-\$5,235
Scenario 1: low service usage	Reduced usage in allied health services and diagnostic imaging services	\$6,131	\$587	-\$5,544
Scenario 2: high service usage	Increased usage in allied health service and diagnostic imaging services	\$7,191	\$2,368	-\$4,823
Scenario 3: diagnostic imaging	Reduced usage in diagnostic imaging service in non-surgical patients	\$6,474	\$1,051	-\$5,422

**Abbreviations:**

**SAD** = subacromial decompression

**Notes:**

The base-case assumptions were taken from utilisation data for item 48951

Scenario 1 assumptions were based on an overall lower rate of physiotherapy and diagnostic imaging as identified in the literature

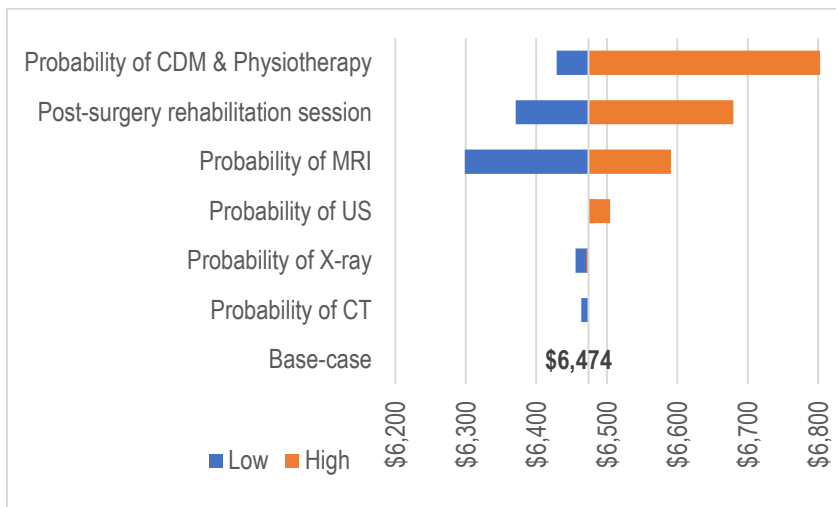
Scenario 2 assumptions were based on an overall higher rate of physiotherapy and diagnostic imaging services as identified in the literature

Scenario 3 involves the exclusion of MRI and CT from active conservative therapy in line with guidelines that do not recommend these services to be available in primary care

The cost comparison shows that the management of subacromial impingement is more expensive when SAD is involved in all scenarios. The cost saving is approximately \$5,000 when using active conservative therapy alone (i.e. intervention without SAD surgery). The greatest contributing factors to this cost difference are hospitalisation costs, and fees and charges directly associated with the surgery. While additional physiotherapy will increase costs in the conservative-only pathway, the cost increments are still not comparable to the cost of surgical intervention. Thus, the use of active conservative therapy is cheaper for the Australian health system. However, it should be noted that in the non-surgical pathway, some cost burdens are transferred to patients and private health insurers. Therefore, active conservative therapy may not be cost-saving from the perspectives of patients and private health insurers. Due the subjective variability in service usage, as well as how much patients and private health insurers are charged in different settings, this burden of cost transfer is highly uncertain.

In addition to the scenario analyses, one-way deterministic sensitivity analyses were undertaken for the 2 SAD treatment pathways. Tornado diagrams were produced to illustrate different cost drivers of the uncertainties in both arms (Figure 1 and Figure 2). For the purposes of the economic analyses, it was assumed that initial physiotherapy (used by all patients) was accessed through the MBS Chronic Disease Management plan (CDM), and physiotherapy used by patients as an alternative to surgery was subsequently provided independently of the MBS by a senior or specialist physiotherapist. The intent was to differentiate between services available through, and outside of the MBS, and to recognise that many clinics advertise different seniority of physiotherapists at different costs. It is acknowledged that access to, use of and payment for physiotherapy services by patients with shoulder impingement pain will vary.

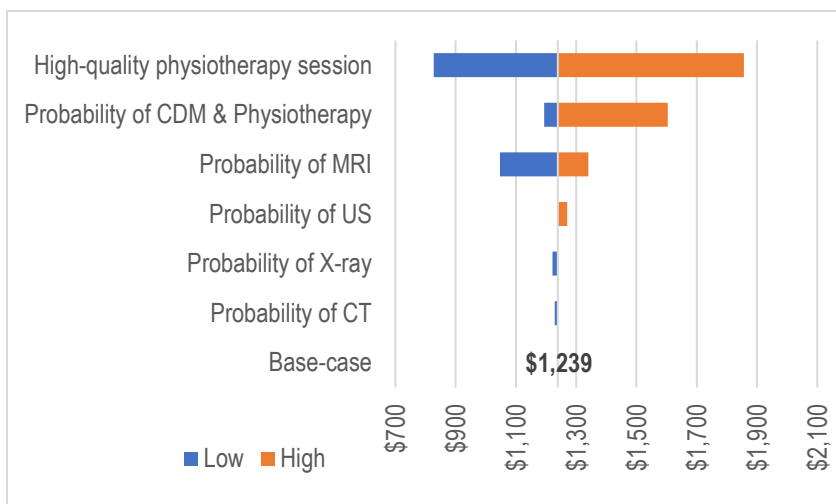
**Figure 1 Tornado diagram of uncertain variables for surgical pathway**



**Abbreviations:**

CDM = chronic disease management plan; CT = computed tomography; MRI = magnetic resonance imaging; US = ultrasound.

**Figure 2 Tornado diagram of uncertain variables for non-surgical pathway**



**Abbreviations:**

CDM = chronic disease management plan; CT = computed tomography; MRI = magnetic resonance imaging; US = ultrasound.

From the sensitivity analysis, we observe that the use of physiotherapy in both the surgical and non-surgical pathways is the main cost driver. This is particularly the case for the non-surgical pathway. This finding reflects the varied and uncertain clinical practice in management of



subacromial impingement, as well as the preference of patients to undertake exercise therapy at home. Use of various diagnostic imaging services is also a small cost driver across both pathways. MRI usage is the most impactful, particularly in the surgical pathway.

## 14. Financial/budgetary impacts

### Financial impacts

The financial implication for MBS SAD surgical services was projected over 6 financial years from 2022 to 2027. A market-share approach was used to predict the number of patients potentially eligible for SAD surgical interventions under the current and proposed SAD service scope. MBS historical claim data as well as AIHW hospital data were used as the basis of this estimate.

Several categories of medical and surgical services relevant to SAD are identified in the MBS. The utilisation of each relevant MBS item was derived via current clinical practice, MBS co-claim patterns (via the data request) and reasonable assumptions. The categorical subtotal costs to the MBS were then aggregated by the cost of surgery, the cost of all relevant perioperative services, and other associated medical services before and after surgery. The financial implication of MBS SAD services was then calculated over the projected 6 financial years. The key results of the base case, plus 4 different plausible scenarios, are presented in Table 12.

**Table 12 Financial implication for MBS SAD services under the base case and all scenarios**

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Base-case scenario	\$6,922,388	\$6,272,417	\$5,622,489	\$4,974,547	\$4,322,653	\$3,672,731
Scenario 1: new SAD item	-\$957,233	-\$860,252	-\$763,270	-\$666,288	-\$569,307	-\$472,325
Scenario 2: full physiotherapy	-\$729,081	-\$656,293	-\$583,504	-\$510,716	-\$437,928	-\$365,592
Scenario 3: restriction for surgery	-\$415,452	-\$372,511	-\$329,569	-\$286,628	-\$243,686	-\$200,745
Scenario 4: full disinvestment	-\$2,578,265	-\$2,336,198	-\$2,094,131	-\$1,852,064	-\$1,609,997	-\$1,367,930

#### Abbreviations

MBS = Medical Benefit Scheme, SAD = subacromial decompression.

#### Notes

Base-case scenario: Informed by the MBS data utilisation and co-claiming for item 48951

Scenario 1: Based on a single consolidated item with a weighted average fee

Scenario 2: Based on scenario 1, but with all patients receiving 3 months rehabilitation and 39% patients not receiving surgery as informed from the literature

Scenario 3: Based on scenario 1, but with services restricted to 55% of patients with radiological signs of impingement, having failed active conservative therapy, as informed from the literature and consultation feedback

Scenario 4: Complete removal of SAD services from the MBS

In the base-case scenario, it is estimated that the full cost of all relevant SAD services in the MBS is over \$6.9 million in 2022, reducing to \$3.7 million in 2027. This is due to the decreasing trend in the number of patients receiving MBS SAD surgical services in the past 5 years. Four alternative scenarios are produced to capture potential modifications of the SAD service scope. All 4 scenarios are aimed to either tighten the patient eligibility for surgery or reduce the scope of the SAD surgical service. The fourth scenario (full disinvestment) proposes to completely remove MBS SAD surgical services and direct patients to receive active conservative management, including physiotherapy. Consequently, these scenarios all lead to cost savings to the MBS and are presented as negative values in Table 12 to quantify their net impact to the MBS.

## 15. Other relevant information

### Review of MBS item utilisation data

A review of the utilisation of SAD services (MBS items 48900, 48903 and 48951) provided insights into patterns of use relative to other services and to provide information on relevant scenarios for budget impact analysis. The output includes information on the utilisation of MBS item use for referrals, diagnostic imaging and treatment.

Two AIHW datasets include information on hospital procedures and healthcare interventions for SAD and arthroscopic SAD, and the hospitals' principal diagnosis for impingement syndrome of the shoulder.

While the AIHW data provide valuable information on hospitalised patients diagnosed with subacromial impingement, the true number of patients with the condition can be underrepresented. Patient diagnosis often occurs in the primary care setting.

Various datasets for MBS services included information on MBS services data for items 48900, 48903 and 48951; MBS co-claiming data for the top 10 claim combinations and the top 10 co-claimed services; MBS diagnostic imaging services and referral information; and MBS patients who received exercise physiology or physiotherapy.

However, co-claimed services related to SAD surgery accessed before this time period would not have been counted and it is therefore likely that the number of services provided to patients for physiotherapy and diagnostic imaging were under-represented in this analysis. This analysis has not included any non-MBS-funded services (e.g. additional physiotherapy services, out-of-pocket diagnostic imaging).

Analysis of MBS utilisation data for MBS items 48900, 48903 and 48951 show the following for financial year 2020–21:

- Co-claiming. The differing claiming patterns of the three SAD items with other surgical services indicated that these items are used differently to one another. MBS 48900 is co-claimed with US or echography in conjunction with a surgical procedure using interventional techniques (55848, 5850 or 55850), which likely indicates the use of this item for image-guided removal of calcium deposits with injection (e.g. lavage) by radiologists or in specialist or GP rooms.
- A range of other shoulder services were commonly claimed with MBS item 48903, such as excision of ganglion cysts, synovectomy of the shoulder and total shoulder replacement. This use of item 48903 in association with services for other shoulder pathologies is likely related to a lack of restriction in the item descriptor.
- MBS 48951 was claimed as a standalone procedure in half of the total top 10 episodes on co-claiming data. Its use is therefore most likely to represent SAD for subacromial impingement in isolation from other shoulder pathology. Shoulder services such as removal of ganglion or cyst, tendon and ligament transfer, and rotator cuff repair were also used in combination with MBS 48951.
- Demographic data. There is variability in population characteristics across MBS items. The proportion of female patients is higher in MBS 48900, while males are more commonly represented in 48951. For item 49803 there is a similar distribution of males and females. The proportion of younger patients (0–54 years) is higher in MBS 48900, whereas for 49803 and 49851 patients age 55–74 are more common.
- Surgical services. For financial year 2020–21, MBS 48951 had the highest number of claims, consistent with historical claims from previous years. There has been a downward

trend in the number of claims over the past 5 years. There is a similar downward trend in the rates of diagnosis of subacromial decompression in Australian hospitals.

- Diagnostic imaging. X-ray and US were the most commonly requested diagnostic imaging procedures for MBS 48900 and 48903, while X-ray and MRI were more common for MBS 48951. CT was rarely used but was most commonly claimed for 48903. Across all 3 surgical items, the average patient received 1.46 services for diagnostic imaging per surgical service.
- Referral patterns. There is variability in the referral patterns for diagnostic imaging across MBS SAD items. A higher proportion of requests came from GPs for MBS 48900, from specialist – orthopaedic surgeons for MBS 48903, and from GP or specialist for MBS 48951. A higher proportion of the requests from GPs were for X-ray and US, while all MRI requests were made by specialists. For 48951, all MRI requests and most US services (96.7%) came from specialists, while 56.1% of X-ray requests came from GPs. This is in line with recommendations of clinical practice guidelines that US and MRI should not be provided in primary care for suspected rotator cuff disease or subacromial impingement. Any non-MBS-funded diagnostic services (e.g. shoulder MRI referred from a GP, paid for out-of-pocket by a patient) has not been identified in this analysis.
- Allied health. Uptake of allied health services (physiotherapy and/or exercise physiology) was generally low, with approximately 20% of all patients accessing these services through the MBS. This may be attributed to the patient's eligibility for a CDM plan, which gives them access to 5 allied health sessions with a Medicare rebate, and likely underrepresents the total number of claims as this analysis was restricted to data from one financial year. Patients who accessed additional physiotherapy privately or outside the CDM were not included in the dataset. Female patients and those age 55–74 were more likely to access these services.

### **Supplementary clinical evidence**

The included studies are supplemented by additional studies. These studies do not add to the primary evidence for effectiveness and safety but provide additional context in terms of predictive and prognostic factors for surgical outcomes, and information related to other populations that may benefit from subacromial decompression that are not represented in the primary analyses. These studies include clinical practice guidelines, RCTs (of other populations and/or other comparators or interventions), non-randomised comparative studies, and case series.

Long-term follow-up of 10 years or more was reported in 7 case series. The rate of repeat surgeries was similar to that reported in RCTs, varying from 3% to 26% across studies. Where reported (2 case series), there was no difference in outcome between short-term (1 or 8 years) or long-term (13 and/or 25 years) follow-up.

Seventeen studies (clinical guidelines, RCTs, non-randomised comparative studies, case series) reported a range of factors considered to be predictive or prognostic of improved outcomes following SAD and for recovery from rotator cuff disorders. This evidence should be treated with caution as none of the identified clinical studies reported being suitably powered to examine subgroups and it is unclear which, if any, improvements reached clinically important differences. Commonly reported factors that led to improved outcomes included older age and a worse clinical score at baseline. No RCT showed clinically significant differences on pre-planned subgroup analyses.

Seven case series were identified which reported the impact of radiological evidence of abnormal morphology, impingement or abrasion. Of these, 2 studies reported that radiological signs of

impingement were consistently associated with a good outcome ( $p < 0.001$ ) or were seen in all patients meeting the set criteria for an improved outcome.

There were few ongoing studies. The FIMPACT trial is continuing to 10-year results (Paavola). One trial is currently recruiting to compare SAD with placebo (sham) procedure in 160 randomised patients who must have completed at least 3 months of supervised shoulder training (NCT04644042, expected year of completion 2026).

## 16. Key issues from ESC to MSAC

### Main issues for MSAC consideration

#### Clinical issues:

- Comparative effectiveness – The evidence suggests there is no difference in effectiveness of SAD compared with active conservative management or placebo, however studies involved broad patient populations and were not powered to investigate subgroups.
- Comparative safety– ESC queried whether SAD could be considered noninferior for comparative safety, given that SAD also involves anesthesia and the risk of peri-operative complications compared with active conservative management. After deliberating, ESC concluded that SAD likely has an inferior safety profile compared to active conservative therapies, but serious adverse events are rare.
- Population – There is some clinical opinion that there may be benefit from SAD in patients who have radiological evidence of a mechanical cause of impingement and who have undergone active conservative management for 6 months with no improvement. However, there is concern about selecting a patient population based solely on clinical acumen without evidence of comparative effectiveness.
- Failure of active conservative management should be more clearly defined to be able to demonstrate no improvement, such as by using the Shoulder Pain and Disability Index (SPADI) or similar score.

#### Economic issues:

- The cost of surgery and associated medical services are the key drivers of the incremental costs. This is partially offset by a reduction in physiotherapy services. The private/public split of costs is uncertain due to limited data on private physiotherapy and GP referred MRI services.
- Overall, ESC did not consider the cost comparison analysis to be useful for decision making as it considered the assumption the acute and chronic populations are comparable to be uncertain.

#### Financial issues:

- All scenarios in the financial and budgetary analysis result in net cost savings to the MBS. MSAC may wish to consider four alternative scenarios proposed in the ADAR:
  - Scenario 1: Based on a single consolidated item with a weighted average fee
  - Scenario 2: Based on scenario 1, but with all patients receiving 3 months rehabilitation and 39% patients not receiving surgery as informed from the literature
  - Scenario 3: Based on scenario 1, but with services restricted to 55% of patients with radiological signs of impingement, having failed active conservative therapy, as informed from the literature and consultation feedback
  - Scenario 4: Complete removal of SAD services from the MBS.

#### Other relevant information:

- ESC considered that the current MBS items do not represent best practice.

## ESC discussion

ESC noted that the purpose of the application was a review of Medicare Benefits Schedule (MBS) items for subacromial decompression (SAD). SAD surgery and rotator cuff repair are commonly performed in Australia and are currently reimbursed through MBS items numbers since 1991. In 2019, the MBS Review Taskforce Orthopaedic Clinical Committee recommended that for shoulder surgery, existing items for SAD and rotator cuff repair should be consolidated (recommendation 74, 75)<sup>12</sup>.

ESC noted the pathway to date for the application. Following, the MSAC's July 2020 review of application 1593 for bovine bioinductive (REGENETEN™) for repair of rotator cuff tears, the MSAC recommended that the MSAC Executive review the MBS item 48903 (standalone subacromial decompression surgery of the shoulder). The department advised that item 48909 (rotator cuff repair including decompression of the subacromial space) also required consideration. During its deliberations, the MSAC Executive noted the results of two recent systematic reviews showed that the clinical benefits of these procedures compared to active conservative management was uncertain and advised the department that a full health technology assessment (HTA) review was required prior to the implementation of the MBS Review Taskforce Orthopaedic Clinical Committee recommendations 74 and 75.

The terms of reference (TOR) for the review include a review of clinical guidelines on the management of rotator cuff disease, utilisation of SAD services, and comparative safety and clinical effectiveness of SAD used in the management of rotator cuff disease. Following consideration by the PICO Advisory Sub-committee (PASC), MBS items for rotator cuff repair (with/without subacromial decompression) were removed from the scope of the current review. This was because current item numbers (e.g. 48906) are already inclusive of rotator cuff repair with or without SAD. Furthermore, the MBS Review Orthopaedic Clinical Committee Report considered different techniques of SAD including the excision of large bursa, acromioplasty and synovectomy to be inherent components of rotator cuff repair and should not be co-claimed. ESC noted the upcoming Australian Rotator Cuff trial (ACTRN12620000789965): a randomised placebo-controlled trial will assess surgical repair of non-acute rotator cuff tears. ESC noted that the current review is to assess SAD as a standalone procedure (not in conjunction with rotator cuff repair).

ESC noted that shoulder pain is a highly prevalent condition in the Australian population. Subacromial shoulder pain accounts for 89% of total shoulder complaints referred to general practitioners and physiotherapists. ESC noted that SAD surgery removes bone or soft tissue that cause the narrowing of the subacromial space, which can be performed with an open or mini-open procedure or via arthroscopy.

ESC noted the current and proposed MBS items for SAD do not nominate a proposed population. During consultation, the Shoulder and Elbow Society of Australia (SESA), recommended that patient selection for acromioplasty should be:

- A failure of nonoperative measures over 4–6 months
- Examination consistent with impingement and with the exclusion of other common causes of shoulder pain such as adhesive capsulitis, long head of biceps tendonitis, osteoarthritis etc.
- Ongoing untenable symptoms

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<sup>12</sup> <https://www.health.gov.au/resources/publications/taskforce-final-report-orthopaedic-mbs-items>

- The demonstration of a mechanical cause for the cuff impingement (e.g. radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion).

ESC noted the population as per the Ratified PICO confirmation is adult patients with symptomatic subacromial shoulder impingement and symptoms unresolved despite active conservative therapy for 6 months. ESC considered that the failure of active conservative management should be more clearly defined to be able to demonstrate no improvement. This could be defined by using the widely used Shoulder Pain and Disability Index (SPADI) or similar score.

ESC noted the current clinical management algorithm. ESC considered that imaging results that indicate a mechanical cause of impingement could be added given its potential importance to identifying the likely patients who may benefit from SAD. ESC noted the comparator, continued active conservative management, involves rest or no treatment, medication for pain and inflammation, physiotherapy, and subacromial injection.

ESC noted the consultation feedback. ESC also noted the statement in the PICO confirmation that multiple tests are commonly used in practice and the reliability of diagnostic tests to identify subacromial impingement may vary with the experience of the examiner. ESC considered that training or evaluation of assessment reliability could be implemented to reduce this variation.

ESC noted that a total of 17 studies (inclusive of 9 randomised controlled trials [RCTs] and 5 case series studies) met the inclusion criteria for assessing the safety and effectiveness of SAD compared with active conservative therapy. The RCTs had a total number of 1,179 randomised participants. Two follow-up publications of the FIMPACT (Paavola) trial and one new RCT are available in addition to those in the Cochrane review<sup>13</sup>. Due to the lack of reporting of safety data in the RCTs, 5 case series with populations greater than 1,000 were used for safety outcomes (but not for effectiveness).

ESC noted that two trials at low risk of bias included the use of sham surgery as a placebo (Beard 2018, Paavola [2018, 2021]). Other trials were at higher risk of bias, commonly due to a lack of protocol, a lack of information regarding randomisation, an inability to blind across treatment populations, and imbalances across reported populations at follow-up. The GRADE certainty of evidence was moderate to high for comparisons to placebo (sham) procedure, and low or very low for comparisons with active conservative therapy.

ESC noted the data on comparative safety, which indicate that adverse event rates are broadly similar for SAD, active conservative management and placebo (sham) procedure. Frozen shoulder occurred with similar rates following SAD, active conservative management and placebo (sham) procedure. The infection rate following shoulder arthroscopy was 0.27%, based on a prospective insurance database of 165,820 patients in the United States. Although there were no comparative data on infection rates, it was noted that patients undergoing active conservative

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<sup>13</sup> Bäck M, Paavola M, Aronen P, Järvinen TLN and Taimela S 2021. Return to work after subacromial decompression, diagnostic arthroscopy, or exercise therapy for shoulder impingement: a randomised, placebo-surgery controlled FIMPACT clinical trial with five-year follow-up. *BMC musculoskeletal disorders*, 22, 889.

Cederqvist S, Flinckila T, Sormaala M, Ylinen J, Kautiainen H, Irmola T, Lehtokangas H, Liukkonen J, Pamilo K, Ridanpaa T et al. 2021. Non-surgical and surgical treatments for rotator cuff disease: A pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation. *Annals of the Rheumatic Diseases*, 80, 796-802.

Paavola M, Kanto K, Ranstam J, Malmivaara A, Inkinen J, Kalske J, Savolainen V, Sinisaari I, Taimela S and Järvinen TL 2021. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: a 5-year follow-up of a randomised, placebo surgery controlled clinical trial. *British journal of sports medicine*, 55, 99-107.

management may receive a subacromial injection, for which infection is a potential adverse event. Therefore the risk of infection is present in both groups. However, ESC queried whether SAD could be considered noninferior for comparative safety, given that SAD also involves anesthesia and the risk of peri-operative complications. After deliberating, ESC concluded that SAD likely has an inferior safety profile compared to active conservative therapies, but serious adverse events are rare.

ESC noted the data on comparative effectiveness. Overall, there were no clear differences between SAD and active conservative management relating to shoulder pain, shoulder function, health-related quality of life or return to work. For shoulder function, compared with active conservative therapy, surgery reaches clinical significance at the 10-year timepoint, with a mean difference in shoulder function scores of 9.59 (95% confidence interval [CI] 1.98 to 17.19). However, this is based on results from 2 trials of very low certainty and so should be treated with caution. Compared with placebo (sham) procedure, SAD did not show a statistically or clinically significant difference on outcomes such as pain, shoulder function, HRQoL and return to work, as indicated by a single study. However, ESC noted that the trial populations may reflect a broader population of patients who were not selected based on defined criteria of pain or function, in particular some studies did not isolate those with pure subacromial impingement which surgeons typically manage with SAD.

ESC noted that the department sought ESC's advice on whether there is a patient population that may benefit from SAD. ESC considered whether a potential patient population may be those who have undergone active conservative management for 6 months with no improvement and who have radiological evidence of a mechanical cause of impingement (such as a magnetic resonance imaging [MRI] scan that indicates a bone spur or hardened soft tissue). ESC noted that there were no studies that indicate that these patients would benefit from SAD. Although the clinical trials were robust in design and showed evidence that SAD's effectiveness was noninferior compared with active conservative management, they involved broader populations and were not powered to investigate subgroups. However, based on clinical acumen, it may be reasonable to consider whether patients with clear radiological evidence of mechanical impingement (MRI is the gold standard) who are not responding to active conservative management may benefit from SAD. ESC also noted that shoulder degeneration or changes are common over time, and the high sensitivity of magnetic resonance imaging (MRI) may result in incidental findings that may not be related to shoulder pain. However, it was noted that most standalone SAD procedures undertaken to manage pure subacromial impingement (that is, excluding other indications including rotator cuff repair) are performed in younger patients aged less than 65 years.

ESC noted there is some clinical opinion that suggests there may be benefit from SAD in patients who have radiological evidence of a mechanical cause of impingement and who have undergone active conservative management for 6 months with no improvement. However, ESC expressed concern about selecting a patient population without evidence of comparative effectiveness based solely on clinical acumen.

ESC noted the economic evaluation, which was a cost comparison and scenario analysis of SAD compared with active conservative management. The cost comparison was based on the framework of a cost-minimisation approach. Key drivers of the model were the cost of surgery and associated medical services. Cost offsets included a reduced need for physiotherapy. ESC considered that the private/public split of costs were uncertain due to limited data on private physiotherapy and GP referred MRI services. ESC noted that the model assumed that patients with acute or chronic shoulder pain were comparable but considered this to be unlikely. Overall, ESC did not consider that the economic model was useful for decision making.

ESC noted the financial and budgetary impacts. The base case scenario indicates a cost to the MBS of \$6.9 million in 2022, reducing to \$3.7 million in 2027. ESC noted there is a decreasing trend in the number of patients receiving SAD services on the MBS in the past 5 years and a similar trend is also observed in Australian hospital data related to the principal diagnosis of subacromial impingement. ESC noted the DCAR suggested that it is possible that this trend may be associated with more rigorous patient selection prior to referral for surgery due to uncertain effectiveness.

All other scenarios in the financial estimates resulted in overall MBS cost savings (see Table 12). MSAC may wish to consider four alternative proposed scenarios:

- Scenario 1: Based on a single consolidated item with a weighted average fee
- Scenario 2: Based on scenario 1, but with all patients receiving 3 months rehabilitation and 39% patients not receiving surgery as informed from the literature
- Scenario 3: Based on scenario 1, but with services restricted to 55% of patients with radiological signs of impingement, having failed conservative therapy, as informed from the literature<sup>14</sup> and consultation feedback
- Scenario 4: Complete removal of SAD services from the MBS

ESC considered that similar to the economic evaluation, the financial analysis is limited by the fact that only 20% of physiotherapy sessions are claimed through the MBS (up to 5 allied health services per calendar year through the chronic disease management plan [CDM] plan). Private services are not considered in these data and therefore the total costs associated with conservative management are likely to be underestimated.

The department informed ESC that there is currently significant utilisation of MBS items 48900, 48903 and 48951, and that stakeholder groups had raised concerns about patient access during the consultation process. Any recommended changes will require significant liaison with stakeholders and patient groups before being implemented.

## 17. Further information on MSAC

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

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<sup>14</sup> Singh *et al.*, 2014. A preoperative scoring system to select patients for arthroscopic subacromial decompression. *Journal of Shoulder & Elbow Surgery*, 23, 1251-6.