Australian Government

Department of Health

# Application Form

# Bovine bioinductive collagen implant for the repair of rotator cuff tear

## (New Request for Public Funding)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au
Website: www.msac.gov.au

# PART 1 – APPLICANT DETAILS

**1. Applicant details (primary and alternative contacts)**

| |
|---|
| Corporation / partnership details (where relevant): Smith & Nephew Pty Ltd |
| Corporation name: Smith & Nephew Pty Ltd |
| ABN: 68 000 087 507 |
| Business trading name: Smith & Nephew Pty Ltd |

**Primary contact name:** REDACTED

| |
|---|
| Primary contact numbers |
| Business: REDACTED |
| Mobile: REDACTED |
| Email: REDACTED |

**Alternative contact name:** REDACTED

| |
|---|
| Alternative contact numbers |
| Business: REDACTED |
| Mobile: NA |
| Email: REDACTED |

**2. (a) Are you a lobbyist acting on behalf of an Applicant?**

☐ Yes
☒ No

**(b) If yes, are you listed on the Register of Lobbyists?**

☐ Yes
☐ No

# PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

**3. Application title**

Bovine bioinductive collagen implant (BCI) for the repair of rotator cuff tear.

**4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)**

The rotator cuff is a group of muscles and tendons that surround the shoulder joint, keeping the head of the upper arm bone (humerus) firmly within the shallow socket of the shoulder. A rotator cuff tear is the partial or full detachment of the tendon that attaches the muscles from the shoulder blade to the head of the humerus. The cause of rotator cuff tears is multifactorial and likely a combination of age-related chronic degeneration of the tendon, direct micro/macro trauma (acute), impingement and/or repetitive or vigorous overhead activity (Micallef 2019). Rotator cuff tears are the most common cause of pain and disability related to the shoulder but can also be asymptomatic. The prevalence of rotator cuff tear increases with age; rotator cuff tears are present in approximately 25% of individuals in their 60s and 50% of individuals in their 80s (Tashjian 2012). The rotator cuff has limited ability for spontaneous healing without repair (Tashjian 2012).

**5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)**

The proposed medical service is the application of a bioinductive collagen implant, designed to induce the formation of new tendon-like tissue that will biologically augment the degenerated rotator cuff tendon. The physical and chemical properties of the scaffold provide a layer of collagen between a flat tendon and the surrounding tissue permitting collagen in-growth into the scaffold and promoting collagen re-modelling with alignment of the collagen fibres in the direction of the stress in the tendon. The scaffold is hydrated in saline and positioned arthroscopically through a small incision over the tendon with one end overlapping the tendon insertion. Tendon and bone staples are used to secure the scaffold in place while the new tissue is being generated. The procedure may also be performed by mini-open surgery. The procedure is performed under general anaesthesia (Bokor et al 2016).

**6. (a) Is this a request for MBS funding?**

☐ Yes
☒ No

REDACTED

**(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?**

☐ Amendment to existing MBS item(s)
☐ New MBS item(s)

**(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:**

N/A

**(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?**

i. ☐ An amendment to the way the service is clinically delivered under the existing item(s)
ii. ☐ An amendment to the patient population under the existing item(s)

iii. ☐ An amendment to the schedule fee of the existing item(s)
iv. ☐ An amendment to the time and complexity of an existing item(s)
v. ☐ Access to an existing item(s) by a different health practitioner group
vi. ☐ Minor amendments to the item descriptor that does not affect how the service is delivered
vii. ☐ An amendment to an existing specific single consultation item
viii. ☐ An amendment to an existing global consultation item(s)
ix. ☐ Other (please describe below):

N/A

**(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?**

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☐ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

**(f) Is the proposed service seeking public funding other than the MBS?**

☐ Yes
☒ No

**(g) If yes, please advise:**

N/A

**7. What is the type of service:**

☒ Therapeutic medical service
☐ Investigative medical service
☐ Single consultation medical service
☐ Global consultation medical service
☐ Allied health service
☐ Co-dependent technology
☐ Hybrid health technology

**8. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:**

N/A

**9. Does your service rely on another medical product to achieve or to enhance its intended effect?**

☐ Pharmaceutical / Biological
☒ Prosthesis or device
☐ No

**10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?**

N/A

**(b) If yes, please list the relevant PBS item code(s):**

N/A

**(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?**

N/A

**(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?**

Trade name: N/A
Generic name: N/A

**11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?**

☐ Yes
☒ No

**(b) If yes, please provide the following information (where relevant):**

Billing code(s): N/A
Trade name of prostheses: N/A
Clinical name of prostheses: N/A
Other device components delivered as part of the service: N/A

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?**

☐ Yes
☒ No

REDACTED

**(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

☐ Yes
☒ No

**(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):**

N/A

**12. Please identify any single and / or multi-use consumables delivered as part of the service?**

Single use consumables:

- 3 clear cannulas
- Single use disposable instrument set comprising: 2 clear lateral cannulas, guide wire, graft delivery system, metal staple delivery instrument; bone stapler

# PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

**13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:**

Type of therapeutic good: Single use medical device
Manufacturer's name: REDACTED
Sponsor's name: REDACTED

**(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

☒ Class III
☐ AIMD
☐ N/A

**14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

**(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**

☐ Yes (if yes, please provide details below)
☒ No
ARTG listing, registration or inclusion number: N/A
TGA approved indication(s), if applicable: N/A
TGA approved purpose(s), if applicable: N/A

**15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?**

☒ Yes (please provide details below)
☐ No
Date of submission to TGA: REDACTED
Estimated date by which TGA approval can be expected: REDACTED
TGA Application ID: REDACTED
TGA approved indication(s), if applicable: The Bioinductive Implant is indicated for the management and protection of rotator cuff tendon injuries in which there has been no substantial loss of tendon tissue.
TGA approved purpose(s), if applicable: The Bioinductive Implant is indicated for the management and protection of rotator cuff tendon injuries in which there has been no substantial loss of tendon tissue.

**16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

☐ Yes (please provide details below)
☐ No
Estimated date of submission to TGA: N/A
Proposed indication(s), if applicable: N/A
Proposed purpose(s), if applicable: N/A

# PART 4 – SUMMARY OF EVIDENCE

***17.*** **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

| | **Type of study design*** | **Title of journal article or research project (including any trial identifier or study lead if relevant)** | **Short description of research (max 50 words)**** | **Website link to journal article or research (if available)** | **Date of publication ***** |
|---|---|---|---|---|---|
| 1. | Non-randomised, single-arm, single-centre Level IV | Bokor. Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up (ACTRN12611001082998) | Repairs of partial-thickness rotator cuff lesions in 13 patients were performed using collagen implant. Evaluated using MRI at 3,6, 12 and 24 months post-operatively.<br>• Significantly improved clinical scores (p=0.01)<br>• Significant (p<0.0001) new tissue formation by 3 months<br>• No tear progression at 24 months | www.ncbi.nlm.nih.gov/pmc/articles/PMC4915456/ | 2016 |
| 2. | Non-randomised, single-arm, single- centre Level IV | Bokor. Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up (ACTRN12611001082998) | Repairs of full-thickness rotator cuff lesions in 9 patients were performed using collagen implant. Evaluated using MRI at 3,6, 12 and 24 months post-operatively.<br>• Clinical scores improved significantly (p <.001)<br>• Significant mean tendon thickness increased (p <.0001)<br>• No re-tears observed during the 24-month follow-up | www.ncbi.nlm.nih.gov/pmc/articles/PMC4617212/ | 2015 |
| 3. | Non-randomised, single-arm, retrospective study Level IV | Arnoczky. Histologic Evaluation of Biopsy Specimens Obtained After Rotator Cuff Repair Augmented with a Highly Porous Collagen Implant | Biopsies of collagen implant/host-tissue constructs from 7 patients undergoing a second arthroscopic procedure after arthroscopic rotator cuff repair augmented with a collagen implant.<br>• increased collagen formation, maturation, and organisation over the surface of the implant at 3 months<br>• newly generated tissue at 6 months | ncbi.nlm.nih.gov/pubmed/27650821 | 2017 |
| 4. | Non-randomised, single-arm, multi-centre Level IV | Schlegel. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial thickness tears: a prospective multicentre study | Repairs of partial-thickness rotator cuff lesions in 33 patients were performed using collagen implant. Evaluated using MRI at 3 and 12 months post-operatively.<br>• Clinical scores improved significantly (p <.0001)<br>• Mean tendon thickness increased by 2.0 mm (p <.0001)<br>• No serious adverse events related to the implant | www.ncbi.nlm.nih.gov/pubmed/29157898 | 2018 |

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise.*

**18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.***

| | Type of study design* | Title of research (including any trial identifier if relevant) | Short description of research (max 50 words)** | Website link to research (if available) | Date*** |
|---|---|---|---|---|---|
| **1.** | Observational registry study<br>Level IV | Bioinductive Implant Database Registry (REBUILD) Registry<br>(NCT02784600) | Registry of 173 patients with partial (N=90) or full-thickness (N=83) rotator cuff lesions who underwent surgery using collagen implant. Post-operative assessments were performed at 2, 6, 12 weeks and 6 and 12 months.<br>• Both groups experienced statistically significant (p<0.001) improvement in VAS, SANE, VR-12 PCS, ASES and WORC scores | clinicaltrials.gov/ct2/show/NCT02784600 | 2019 |

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

# PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Shoulder and Elbow Society of Australia

20. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    Not applicable. The comparator service(s) are provided by the same health professionals; i.e., orthopaedic surgeons.

21. **List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    None

22. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    There are no other relevant sponsor(s) and / or manufacturer(s) that produce similar products relevant to the proposed medical service.

23. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    Name of expert 1: REDACTED

    Telephone number(s): REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    Name of expert 2: REDACTED

    Telephone number(s): REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    *Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.*

# PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

***PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION***

**24. Define the medical condition, including providing information on the natural history of the condition and a high-level summary of associated burden of disease in terms of both morbidity and mortality:**

The rotator cuff is a group of four muscles and their tendons (supraspinatus, infraspinatus, teres minor, and subscapularis) at the shoulder joint which form a multilayered horseshoe shape cuff around the head of the humorous bone (Clark and Harryman 1992). Rotator cuff injury can range from simple inflammation to tears of the muscles or tendons. Rotator cuff tears may result due to a degeneration of the tendon quality or due to trauma, where a tear arises from a major injury to otherwise healthy tissue. Several risk factors have been identified in predisposing individuals to the development of rotator cuff tears; increasing patient age, smoking, hypercholesterolemia, and family history. Each of these may play an additive role to the underlying influence of age-related degeneration in the development of rotator cuff disease. The incidence of cuff tears ranges from 5 to 40% (Matsen 2004, Neer 1983), however not all rotator cuff tears are symptomatic, so the true incidence is difficult to determine. Approximately one third of silent rotator cuff tears will become symptomatic (Yamaguchi 2001).

In partial thickness tears, some of the tendon attachment has ruptured but some fibres remain attached to the bone. Such tears can be articular-sided (Partial Articular Sided Rotator Cuff Tears or PASTA lesions), bursal side or intra-tendinous (seen only on imaging studies) (Bollier 2012). The literature demonstrates that articular-sided tears are at least twice as common as bursal-sided tears and that most partial thickness tears involve the supraspinatus tendon (Modi 2012). Partial-thickness tears are 2-3 times more likely, and often much more painful, than full-thickness tears (Sher et al., 1995), where the tendon is no longer connected to the bone.

The spontaneous healing of untreated rotator cuff tears is rare (Mall 2010, Lo 2004, Tashjian 2012) and without intervention, a partial thickness tear is likely to enlarge and propagate into full-thickness tears (Washburn et al, 2017, Sambandam 2012). Progression of symptomatic partial thickness tears to full thickness tears with non-operative treatment has been seen in 18% of patients followed up for over 1 year, with a further 34% exhibiting increase in partial tear size (Yamanaka and Matsumoto, 1994). Because increased tear size and poorer muscle quality are associated with poorer healing after surgical repair, repair before progression may improve outcomes (Tashjian 2012). The risk of tear progression has been shown to correlate with percentage tendon thickness at presentation with progression observed in 55% of patients with ≥50% tearing of tendon thickness at presentation compared to 14% tear progression in those who had <50% tearing (Denkers et al., 2012).

If left untreated, shoulder problems and pain can lead to significant disability, limitations in activity and restrict participation in major life areas such as work and employment, education, community, social and civic life. In the United States, there were 4.5 million physician visits and approximately 40,000 inpatient procedures for problems of the rotator cuff, with a mean cost of $14,000 per case in 2002 (Oh 2007). An economic evaluation investigating the cost-effectiveness of rotator cuff repair compared with nonoperative treatment for symptomatic full-thickness rotator cuff tears resulted in net societal cost savings for patients under the age of sixty-one years and greater QALYs for all patients (Mather 1993), illustrating that that rotator cuff repair may have an important role in mitigating the societal burden of rotator cuff disease (Mather 1993).

**25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:**

Typically, patients with rotator cuff tears present to their general practitioner with shoulder instability, pain and/or weakness and decreasing shoulder power and function (Sambandam 2015). Rotator cuff tears most

frequently occur with general wear and tear, and most people usually don't remember injuring their shoulder. These "degenerative tears", if not associated with arm weakness, may be successfully treated without surgery. This involves avoiding overhead activities, regular simple pain relief (e.g. NSAIDs) and gentle physiotherapy. In more severe cases, increased pain relief using corticosteroid injections, may be used (Oliva 2015). If a rotator cuff tear is suspected, early referral to a physiotherapist may be appropriate (Brun 2012). Referral for imaging may also be warranted where there is evidence or suspected serious damage/disease (NZGG, 2004; Shanahan and Sladek, 2011).

When symptoms fail to improve following a minimum of 3 months of conservative treatment, or where tears have occurred from sudden trauma or acute injury and is impacting on comfort and function, referral to an orthopaedic surgeon for further review and possible surgical repair of the tear as indicated (Brun 2012). The orthopaedic surgeon will determine treatment strategies for the rotator cuff repair primarily based on the location, anatomy and the size of the defect, with 'surgery timing', functionality, age and gender as important secondary considerations (Oliva 2015).

Consistent with the clinical management pathway provided in Appendix A and discussed in Q.26, the proposed patient populations for the bioinductive collagen implant for the treatment of rotator cuff tears is as follows:

*Patients with full thickness or partial thickness rotator cuff tears which is unresponsive to conservative treatment for a minimum of 3 months.*

**26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):**

The current clinical management pathway for the purposes of this application was established after consultation with a key opinion leader given that there are currently no Australian specific guidelines on the repair of rotator cuff tears (provided in Appendix A).

Optimal treatment of rotator cuff tear is multifactorial and influenced by several factors including age, etiology of injury, size and location of tear. Typically, patients with rotator cuff tears present to their general practitioner with shoulder instability, pain and/or weakness and decreasing shoulder power and function (Sambandam 2015). In patients where evidence of cuff disease has been demonstrated via ultrasound and/or x-rays, in most cases, the initial treatment is conservative non-surgical management of symptoms which includes avoiding overhead activities, physical therapy and reducing pain and inflammation using nonsteroidal anti-inflammatory drugs or corticosteroid injections (Micallef 2019, Beaudreil 2010).

Patients that have symptomatic shoulder pain, despite 3 months of conservative management, are referred to an orthopaedic surgeon for consideration of surgical repair.

Standard surgical treatment for full-thickness tears, arthroscopically or mini-open surgery, involves reattaching the muscle to the bone using anchors and sutures.

Standard surgical treatment for partial thickness rotator cuff repair has evolved from simple arthroscopic debridement to trans-tendon arthroscopic repair and completion of the partial tear and repair of the newly created full-thickness tear (take down and repair) (Bollier 2012). The take down and repair procedure involves artificially completing the tear during the surgery followed by standard rotator cuff repair using anchors and sutures, whereas trans-tendon repair maintains the intact lateral portion of the tendon while repairing the medial aspect of the tendon (Woods 2014).

The application of BCI is provided as part of standard surgical repair of partial or full-thickness rotator cuff tears and can be performed arthroscopically or via a mini-open approach. Importantly, the application of BCI in partial thickness tear means there is no need for the take-down and repair approach. The application of BCI induce new tendon-like tissue formation and create an environment conductive to the healing of partial-thickness cuff tears (Bokor et al 2016).

Some patients may not be eligible for surgery or may have a preference to not have surgery. In this instance, conservative management is continued till such a time when a patient becomes eligible for surgery.

***PART 6b – INFORMATION ABOUT THE INTERVENTION***

**27. Describe the key components and clinical steps involved in delivering the proposed medical service:**

The proposed medical service is the application of a bovine BCI for the treatment of full- thickness and partial-thickness rotator cuff tears. The details of the key components and clinical steps of the intervention specifically refer to the use of bovine BCI.

Bioinductive collagen patch augmentation for the treatment of rotator cuff tears, is performed under general anaesthesia in the hospital setting. The procedure can be performed arthroscopically (minimally invasive keyhole surgery) or as mini-open surgery (which involves a small incision typically 3 to 5 cm long). Arthroscopic and mini-open repair surgical techniques for the management of rotator cuff repair are associated with similar outcomes and can be used interchangeably based on the patient and rotator tear characteristics (Morse 2008, Huang 2016).

The key surgical steps in arthroscopic bioinductive patch augmentation are as follows:

1. Diagnostic arthroscopy is performed.
2. Tendon markers along the anterior edge of the supraspinatus are placed in a percutaneous fashion.
3. Entry is made into the subacromial space, and bursectomy is performed through a standard lateral portal.
4. A 5-mm guidewire is placed at the lateral edge of the rotator cuff footprint.
5. The graft is hydrated for 1 minute
6. The graft is loaded into the delivery instrument.
7. The graft is introduced until the red button becomes prominent.
8. The graft is deployed.
9. A second lateral cannula is placed just off the lateral edge of the acromion.
10. Soft-tissue staples are placed through the graft into the underlying rotator cuff.
11. The tendon markers are removed.
12. A bone stapler awl is used to tension the graft from the lateral portal.
13. The bone staples are placed.
14. The instruments are removed, and the wounds are closed.

Following the procedure, standard pain management measures should be undertaken. The postoperative protocol is immediate range of motion as tolerated, with the patient using a sling for comfort. Strengthening can begin once full range of motion has returned.

**28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?**

The proposed medical service, bioinductive collagen implant does include a registered trademark component, which is a bovine collagen implant available in Australia.

**29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

The proposed medical service has a prosthesis component to it and involves the application of the collagen scaffold during surgery to repair rotator cuff tears.

**30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):**

The medical service is intended to be performed once. There are no current limitations on the provision of the proposed medical service with respect to accessibility.

**31. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:**

The healthcare resources required at the same time as the proposed medical service include administration of anaesthesia (patients are under general anaesthesia) and overnight hospitalisation.

**32. If applicable, advise which health professionals will primarily deliver the proposed service:**

The procedure is performed by orthopaedic surgeons.

**33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:**

N/A

**34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:**

Only orthopaedic surgeons perform the procedure.

**35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:**

The procedure is performed by orthopaedic surgeons.

**36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):**

- ☒ Inpatient private hospital (admitted patient)
- ☒ Inpatient public hospital (admitted patient)
- ☐ Private outpatient clinic
- ☐ Public outpatient clinic
- ☐ Emergency Department
- ☐ Private consulting rooms - GP
- ☐ Private consulting rooms – specialist
- ☐ Private consulting rooms – other health practitioner (nurse or allied health)
- ☐ Private day surgery clinic (admitted patient)
- ☐ Private day surgery clinic (non-admitted patient)
- ☐ Public day surgery clinic (admitted patient)
- ☐ Public day surgery clinic (non-admitted patient)
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

**(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:**

The procedures are performed in the hospital inpatient setting (private and public) with overnight hospitalisation.

**37. Is the proposed medical service intended to be entirely rendered in Australia?**

- ☒ Yes
- ☐ No – please specify below

***PART 6c – INFORMATION ABOUT THE COMPARATOR(S)***

**38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):**

REDACTED. Thus, it is proposed that standard surgery will be the comparator to BCI in this Application.

As mentioned in response to Q26 above, the clinical pathway indicates that standard surgery is the comparator to BCI, which involves arthroscopically or by mini-open means reattaching the muscle to the bone using anchors or sutures. The decision to perform surgical repair is dependent on clinical and morphological factors, and patient characteristics, patient eligibility and preference (Beaudreil 2010).

Different procedures are involved for full-thickness and partial thickness tears. For full-thickness tears, surgery involves reattachment of the muscle to the bone using anchors and sutures. For partial-thickness tears, the take down and repair procedure involves artificially completing the tear followed by standard rotator cuff repair, whereas trans-tendon repair maintains the intact lateral portion of the tendon while repairing the medial aspect of the tendon (Woods 2012). It has been suggested that takedown and repair or trans-tendon repair of partial articular-sided rotator cuff tears should be considered when the tear depth exceeds 50% (Bollier 2012).

**39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?**

☒ Yes (please list all relevant MBS item numbers below)
☐ No

**Table 1 Current MBS item numbers for procedures related to shoulder reconstruction including rotator cuff repair**

| MBS item # | Descriptor | Fee |
|---|---|---|
| 48960 | SHOULDER, reconstruction or repair of, including repair of rotator cuff by arthroscopic acromioplasty; or resection of acromioclavicular joint by separate approach when performed - not being a service associated with any other procedure of the shoulder region | $941.45 |
| 48906 | SHOULDER, repair of rotator cuff, including excision of coraco-acromial ligament or removal of calcium deposit from cuff, or both - not being a service associated with a service to which item 48900 applies | $564.85 |
| 48909 | SHOULDER, repair of rotator cuff, including decompression of subacromial space by acromioplasty, excision of coraco-acromial ligament and distal clavicle, or any combination, not being a service associated with a service to which item 48903 applies | $753.25 |
| 48918 | SHOULDER, total replacement arthroplasty of, including any associated rotator cuff repair | $1,506.45 |

**40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):**

As mentioned in response to Q26 above, the clinical pathway indicates that standard surgery is the comparator to BCI, which involves arthroscopically or by mini-open means reattaching the muscle to the bone using anchors or sutures. Standard surgical treatment for full-thickness tears involves arthroscopically or via mini-open surgery means, reattaching the muscle to the bone using anchors and sutures. Standard surgical treatment for partial thickness rotator cuff repair includes both take down and repair surgery or

trans-tendon repair surgery. After receiving surgery patients are followed up 3 months after surgery as routine practice. A repeat procedure may be performed under the discretion of the surgeon if the repair is considered to have failed.

**41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

☒ In addition to (i.e. it is an add-on service)
☐ Instead of (i.e. it is a replacement or alternative)

As noted above, and in response the Q6 above, this application does not seek to create a new MBS item number or amend an existing MBS item number. The descriptor of the currently listed MBS items for the repair of rotator cuff of the shoulder, including 48960, 48906, 48918 and 48909, encompass the proposed service, the application of the BCI.

**(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:**

N/A

**42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):**

After receiving full-thickness or partial-thickness rotator cuff tear surgical repair with the application of BCI, patients are generally followed up 3 months after surgery as routine practice. If patents are still presenting with symptoms and are still symptomatic after 6 months, further imaging with MRI is considered. Based on key opinion leader advice, the recovery and physical rehabilitation with the application of BCI instead of using traditional methods is quicker. It has been suggested that patients who receive surgery with BCI only need 1 week in a sling, with 6 weeks rehabilitation compared to 6 weeks in a sling and between 6 – 9 months recovery with standard surgery. This provides a significant opportunity for patients to return to their usual daily activities including work quicker. Furthermore, recovery is considered to be similar whether the arthroscopic or mini-open surgery procedure was used.

Schlegel et al., (2018) reported that none of the partial thickness tears repaired using BCI, in the patients who followed the post-operative rehabilitation protocol, needed any revision surgery through to the 1-year follow-up. No patient was worse off after having their rotator cuff tears repaired using BCI and all patients showed progressive tendon maturation over the 1-year follow-up, which indicated that the new tissue was indistinguishable from the underlying tendon.

***PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME***

**43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):**

Compared with standard surgical repair, the application of a bovine BCI in the repair of full-thickness and partial thickness tears is expected to result in superior effectiveness (functional) outcomes with similar safety.

**44. Please advise if the overall clinical claim is for:**

☒ Superiority
☐ Non-inferiority

**45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

**Safety Outcomes:**

- Procedural complications
- Longer-term adverse events
- Revision surgery

**Clinical Effectiveness Outcomes:**

Functional outcomes:

- American Shoulder and Elbow Surgeons standardized From for the Assessment of the Shoulder (ASES)
- Constant-Murley shoulder score
- Shoulder pain
- Post-operative physical therapy
- Post-operative return to activities
- Single Assessment Numeric Evaluation (SANE)

Imaging outcomes

- Tendon thickness
- Size of the cuff defect (tear size)

Quality of life

Cost-effectiveness

- Resource utilisation (surgical costs, diagnostic test, follow-up physiotherapy rehabilitation, pain management medication, indirect costs (work days lost)
- Health related quality of life quality adjusted life year.

# PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

**46. Estimate the prevalence and/or incidence of the proposed population:**

Shoulder pain is the third most common musculoskeletal complaint reported to general practitioners in primary care settings (Unwin 1998, van der Windt 1995) with an estimated incidence of 19 per 1000 patients per year. It has been estimated that 65–70% of all shoulder pain is due to rotator cuff complaints (Shanahan & Sladek, 2011).

Prevalence figures of rotator cuff disease and tears across the literature is varied. Cadaver and autopsy dissections have revealed a prevalence of rotator cuff tendon defects ranging from 5% to almost 40% (Matsen 2004, Neer 1983). A prevalence of supraspinatus full-thickness and partial thickness tears of 7% and 13%, respectively was observed, based on a series of 249 cadavers (Yamanaka and Fukada 1987). Other studies have reported the prevalence of partial thickness tears ranging from 13% to 32% with higher prevalence typically observed with increasing age (Fukuda 2000, Sano 1999, Sher 1995).

**47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:**

The proposed medical service is intended to be delivered once only per shoulder.

**48. How many years would the proposed medical service(s) be required for the patient?**

The proposed medical service is intended to be delivered once per shoulder.

**49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:**

It is considered that there are four MBS item numbers under which rotator cuff repair could currently be claimed; 48960, 48906, 48909 and 48918. These items were utilised a total of 17,632 times in the 2017-18 financial year, with little to no growth in utilisation in recent history (Table 2).

**Table 2 MBS items under which rotator cuff repair may be claimed**

| MBS item | MBS descriptor | Utilisation | | | |
|---|---|---|---|---|---|
| | | 2014-15 | 2015-16 | 2016-17 | 2017-18 |
| 48960 | SHOULDER, reconstruction or repair of, including repair of rotator cuff by arthroscopic acromioplasty; or resection of acromioclavicular joint by separate approach when performed - not being a service associated with any other procedure of the shoulder region | 9,665 | 9,521 | 9,176 | 9,258 |
| 48906 | SHOULDER, repair of rotator cuff, including excision of coraco-acromial ligament or removal of calcium deposit from cuff, or both - not being a service associated with a service to which item 48900 applies | 2,610 | 2,463 | 2,538 | 2,585 |
| 48909 | SHOULDER, repair of rotator cuff, including decompression of subacromial space by acromioplasty, excision of coraco-acromial ligament and distal clavicle, or any combination, not being a service associated with a service to which item 48903 applies | 2,490 | 2,340 | 2,153 | 2,041 |

| MBS item | MBS descriptor | Utilisation | | | |
|---|---|---|---|---|---|
| | | 2014-15 | 2015-16 | 2016-17 | 2017-18 |
| 48918 | SHOULDER, total replacement arthroplasty of, including any associated rotator cuff repair | 2,575 | 2,903 | 3,321 | 3,748 |
| Total | | 17,340 | 17,227 | 17,188 | 17,632 |

However, as evident in Table 2, item numbers 48960 and 48918 are **not** specific to rotator cuff repair only. These items also including shoulder reconstruction, resection and replacement and therefore only a proportion of claims under these items relate to rotator cuff repair.

Due to the MBS items not being specific to rotator cuff repairs only, alternative sources were derived that reported the incidence of rotator cuff repair in countries expected to have similar demographics and patient characteristics to those of Australia. Paloneva (2015) reported a nationwide incidence of rotator cuff repair of 131 per 100,000 in Finland, whilst Jensen (2017) reported a rotator cuff repair incidence of 120 per 100,000 across the U.S. Medicare population.

Applying an incidence of 131 per 100,000, from Paloneva (2015), to the 2017 Australian population results in an estimated 25,013 procedures nationally, including both public and private procedures (Table 3). An estimated 45% of the Australian population was privately insured in December 2018 (APRA 2019). Applying this distribution to the total estimated procedures, 25,013, it is estimated that 11,256 (25,013 × 0.45) rotator cuff repairs were performed in a private setting in Australia in 2017.

Assuming initial uptake of REDACTED in Year 1 it is estimated REDACTED BCI procedures will be performed in a private setting in Year 1.

**Table 3 Estimated utilisation of BCI in year 1**

| Variable | 2017 | 2018 | 2019 | 2020 (year 1) |
|---|---|---|---|---|
| Total Australian population | 24,600,777 | 25,015,825 | 25,444,104 | 25,873,480 |
| Australian population aged 18+ | 19,093,688 | 19,427,762 | 19,768,158 | 20,100,838 |
| Incidence of rotator cuff repair per 100,000[a] | 131 | 131 | 131 | 131 |
| Estimated incident population | 25,013 | 25,450 | 25,896 | 26,332 |
| Prop. of procedures performed in private setting | REDACTED | REDACTED | REDACTED | REDACTED |
| Total rotator cuff repairs in private setting[b] | 11,256 | 11,453 | 11,653 | 11,849 |
| Uptake of BCI application | REDACTED | REDACTED | REDACTED | REDACTED |
| Estimated utilisation of BCI application | REDACTED | REDACTED | REDACTED | REDACTED |

[a] Paloneva 2015. Increasing incidence of rotator cuff repairs—A nationwide registry study in Finland. ncbi.nlm.nih.gov/pmc/articles/PMC4531533/pdf/12891_2015_Article_639.pdf

[b] APRA. Private Health Insurance Statistical Trends - Membership December 2018. apra.gov.au/publications/private-health-insurance-statistical-trends

**50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:**

Assuming the initial uptake of REDACTED in Year 1 (Table 3), is linearly increasing to REDACTED in Year 4, it is estimated that REDACTED BCI procedures will be performed in a private setting in Year 2 increasing to REDACTED by Year 4 (Table 4).

There are no apparent constraints in the health care system that would impact on uptake. The risk of leakage is expected to be low given the proposed indication include both full thickness and partial thickness tears, both of which are objectively diagnosed using MRI. It is unlikely that patients without symptoms would elect to undergo surgery.

**Table 4 Estimated uptake of BCI in the next three years**

| | **2021 (year 2)** | **2022 (year 3)** | **2023 (year 4)** |
|---|---|---|---|
| Total Australian population | 26,301,274 | 26,727,025 | 27,147,199 |
| Australian population aged 18+ | 20,429,953 | 20,757,917 | 21,082,471 |
| Incidence of rotator cuff repair per 100,000[a] | 131 | 131 | 131 |
| Estimated incident population | 26,763 | 27,193 | 27,618 |
| Prop. of procedures performed in private setting | REDACTED | REDACTED | REDACTED |
| Total rotator cuff repairs in private setting[b] | REDACTED | REDACTED | REDACTED |
| Uptake of BCI application | REDACTED | REDACTED | REDACTED |
| Estimated utilisation of BCI application | REDACTED | REDACTED | REDACTED |

[a] Paloneva 2015. Increasing incidence of rotator cuff repairs—A nationwide registry study in Finland. www.ncbi.nlm.nih.gov/pmc/articles/PMC4531533/pdf/12891_2015_Article_639.pdf

[b] APRA. Private Health Insurance Statistical Trends - Membership December 2018. www.apra.gov.au/publications/private-health-insurance-statistical-trends

# PART 8 – COST INFORMATION

**51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:**

Table 5 provides breakdown of estimated procedure costs associated with application of bioinductive collagen implant for the treatment of rotator cuff tear. The provision of the proposed medical service, bioinductive collagen implant for the treatment of rotator cuff tear, is estimated to cost REDACTED. Cost estimates are comprised of the bioinductive collagen implant, the procedure itself (MBS 48960) and anaesthesia. The cost of the procedure itself is modelled based on MBS item 48960 as it is likely to be similar in resource utilisation to that of the proposed procedure. The cost of consumables (Q.12), is not included, however is expected to be small given these consumables are standard equipment These estimates will be confirmed in an SBA.

**Table 5** Costs associated with providing bioinductive collagen implant for the treatment of rotator cuff tear

| Row | Parameters | Cost | Source/calculation |
|---|---|---|---|
| A | Bioinductive collagen implant | REDACTED | REDACTED |
| B | Pre-anaesthesia consultation | $43.65 | MBS item 17610 |
| C | Initiation anaesthesia | $99.00 | MBS item 21622 |
| D | Arthroscopic surgery including application of BCI | $941.45 | MBS item 48960 |
| E | Anaesthesia (26-30 minutes)[a] | $39.60 | MBS item 23023 |
| **F** | **Total** | REDACTED | **A+B+C+D+E** |

BCI=bioinductive collagen implant

[a]Given the estimated time of the procedure is 15-30 minutes (Q52).

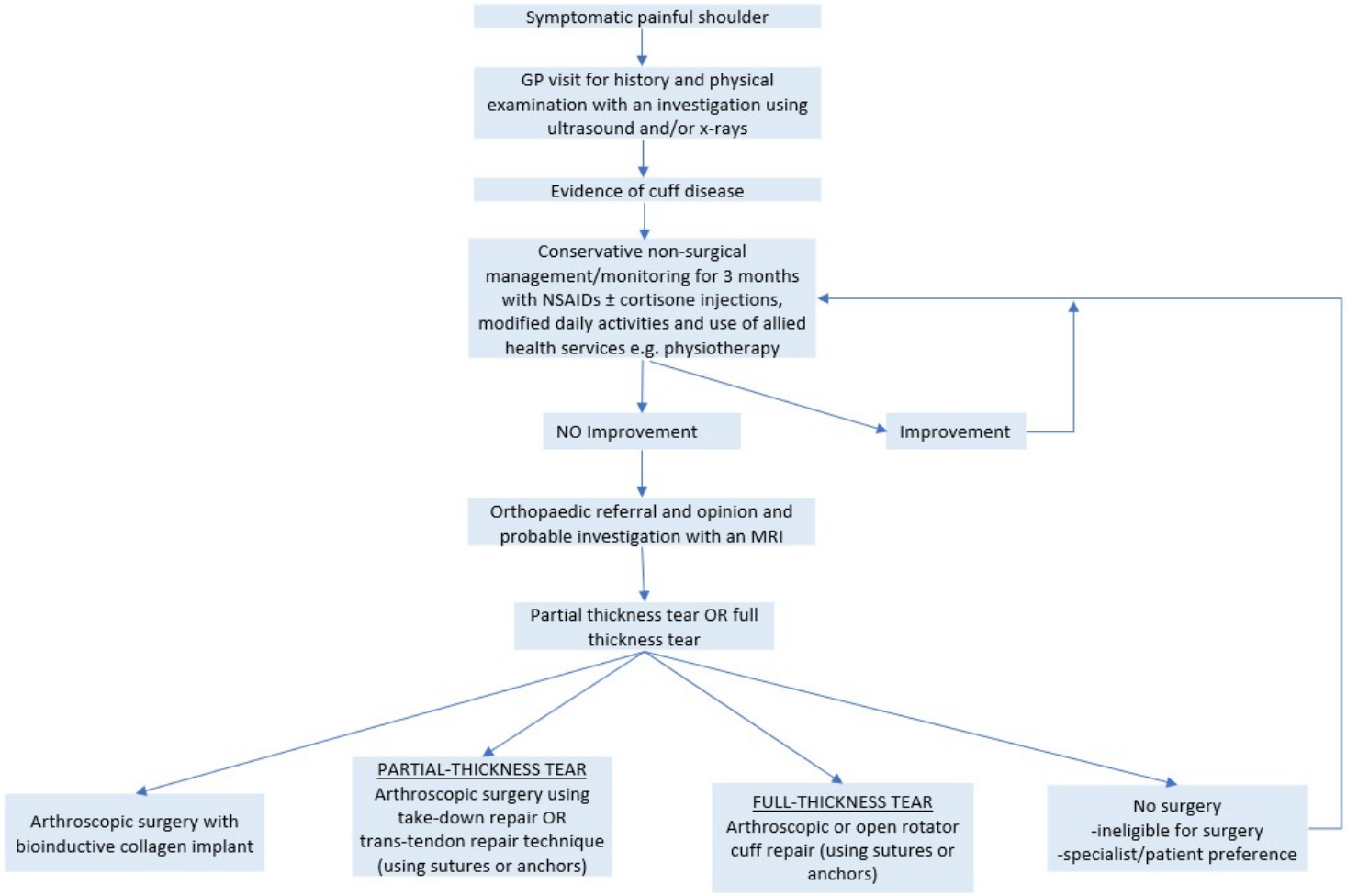
**52. Specify how long the proposed medical service typically takes to perform:**

According to KOL feedback, the average duration of the surgery is 15-30 min.

**53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.**

As previously stated in Q.6A, REDACTED This application does not seek to create a new MBS item number or amend an existing MBS item number. The descriptor of the currently listed MBS items 48960, 48906 and 48909 for repair of rotator cuff of the shoulder encompass the proposed service. REDACTED

# APPENDIX A


Symptomatic painful shoulder
GP visit for history and physical examination with an investigation using ultrasound and/or x-rays
Evidence of cuff disease
Conservative non-surgical management/monitoring for 3 months with NSAIDs ± cortisone injections, modified daily activities and use of allied health services e.g. physiotherapy
NO Improvement
Improvement
Orthopaedic referral and opinion and probable investigation with an MRI
Partial thickness tear OR full thickness tear
Arthroscopic surgery with bioinductive collagen implant
PARTIAL-THICKNESS TEAR
Arthroscopic surgery using take-down repair OR trans-tendon repair technique (using sutures or anchors)
FULL-THICKNESS TEAR
Arthroscopic or open rotator cuff repair (using sutures or anchors)
No surgery
-ineligible for surgery
-specialist/patient preference

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