MSAC Application 1593.1

Bioinductive implant for the repair of rotator cuff tear

Application or referral for other medical service or health technology

MSAC application number:
1593.1

Application title:
REGENETEN bioinductive implant for the repair of rotator cuff tear

Submitting organisation:
Smith & Nephew Pty Limited

Submitting organisation ABN:
68000087507

Application description

Succinct description of the medical condition/s:
A rotator cuff tear (RCT) 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 RCT 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. RCTs 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. Key risk factors for rotator cuff tear include age, cigarette smoking, hypercholesterolaemia, diabetes mellitus and genetic predisposition RCTs are present in approximately 25% of individuals in their 60s and 50% of individuals in their 80s. The rotator cuff has limited ability for spontaneous healing without repair.

Succinct description of the service or health technology:
The REGENETEN implant, when used in isolation (partial-thickness tears) or as an adjunct to a mechanical repair (full-thickness tears), provides a porous scaffold for the formation of new tendon-like tissue. REGENETEN supports the body's natural healing response to facilitate new tendon-like tissue growth and change the course of rotator cuff tear progression. As the newly formed tissue begins to take up more local stress, a natural cell-based remodelling of the extracellular matrix occurs, and the implant is resorbed within six months (Arnoczky et al., 2017). The load sharing abilities of the new tendon-like tissue decreases the strain in the native tendon to allow for tendon healing and functional gains(Mayo Clinic, 2019). REGENETEN is positioned arthroscopically, tendon and bone staples secure the scaffold in place while the new tissue is being generated. The procedure is performed under general anaesthesia and may be performed by mini-open surgery (Bokor et al., 2019).

Application contact details

Are you applying on behalf of an organisation, or as an individual?
Organisation

Is the applicant organisation the organisation you are representing in the HPP today?
Yes

Applicant organisation name:
Smith & Nephew Pty Limited

Application details

Please select the program through which the health technology would be funded:
Prostheses List

Please provide justification for selecting the above program:
In PSD 1593, MSAC noted that the application came from PLAC, which requested that MSAC perform a

full health technology assessment for the listing of bioinductive collagen implant (REGENETEN™) on the Prostheses List (PL) for the repair of rotator cuff tear.

The Prostheses List application will be lodged via PLMS by the 14 May 2023 cut-off date as the HPP is not available for PL applications until September 2023.

We are of the impression that this application will bypass PASC as the PICO has been amended to introduce newly available evidence however, the PICO criteria has not drastically changed. We are waiting confirmation of this from The Executive Meeting on 21 April 2023.

What is the type of service or health technology?
Therapeutic

PICO set

Population

Describe the population in which the proposed health technology is intended to be used:
The population that relates to the Prostheses List request are patients who receive a bioinductive collagen implant (BCI) (REGENETEN™), used with surgical repair, who have symptomatic rotator cuff tears of the shoulder. Specifically, there are two subpopulations which can be grouped by depth of the rotator cuff tear:

- Subpopulation 1: Patients with symptomatic partial-thickness rotator cuff tear (PTRCT) where there is no substantial loss of tissue who have failed at least three months of conservative (non-surgical) management and are considered eligible for (or indicated for) surgical repair
- Subpopulation 2: Patients with symptomatic full-thickness rotator cuff tear (FTRCT) where there is no substantial loss of tissue who have failed at least three months of conservative (non-surgical) management and are considered eligible for (or indicated for) surgical repair.

Select the most applicable medical condition terminology (SNOMED CT):
Traumatic rupture of rotator cuff

Intervention

Name of the proposed health technology:
REGENETEN

Comparator

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). This include identifying health care resources that are needed to be delivered at the same time as the comparator service:

Subpopulation 1:

Standard arthroscopic surgical repair (without bovine BCI), with repair performed using standard sutures or anchors, using two techniques:

- Take-down repair; OR
- Trans-tendon repair

Subpopulation 2:

Standard surgical repair (without bovine BCI), with repair performed using standard sutures or anchors, performed arthroscopically or with 'mini-open' approach

Different procedures are involved for full-thickness and partial thickness tears. Standard surgical repair in patients with PTRCTs includes debridement, diagnosis and bursectomy; followed by surgical repair of the tendon using a trans-tendon or take-down technique. Trans-tendon repair involves maintaining the intact lateral portion of the tendon while repairing the medial aspect of the tendon, this method is technically advanced and is not commonly adapted in clinical practice. Take-down repair involves artificially completing the tear during the surgery followed by standard rotator cuff repair using anchors and sutures ((MSAC), 2020). 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% (M. Bollier & K. Shea, 2012). These surgical treatment options for PTRCT are limited by the degenerative nature of the underlying tendon and may require extensive intervention that can alter the anatomic footprint. The complexity of available techniques to address these issues led to the development of a resorbable collagen implant (REGENETEN), which can be used to create a bioinductive repair of partial-thickness tears (Schlegel et al., 2021). PASC noted REGENETEN replaces the need for trans-tendon repair and take-down repair (i.e. standard surgical repair) for patients with a PTRCT. However, it does not replace the need for debridement and bursectomy (i.e. REGENETEN is performed in addition to debridement and bursectomy) (Department of Health, 2019).

Standard surgical repair in patients with FTRCTs includes debridement, diagnosis and bursectomy; followed by reattaching the muscle to the bone using anchors and sutures.

Previous MSAC Commentary stated that the comparators are appropriate and consistent with the ratified PICO confirmation. The comparators are hospital based – when performed in the private setting they are associated with MBS item numbers (48960, 48906 and 48909) ((MSAC), 2020).

Outcomes

Outcome description - please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Current treatment options for RCT include conservative and surgical repair (standard arthroscopic surgical repair) that do not address factors that lead to progression of degenerative disease. The introduction of REGENETEN to the RCT patient management algorithm will provide

clinicians with an alternative to standard arthroscopic surgical repair (take-down or trans-tendon in PTRCT, or sutures or anchors in FTRCT) that improves the quality of outcomes for patients with RCTs, whilst simultaneously reducing the economic burden to the health system and broader economy from lost productivity. For PTRCT, when REGENETEN Implant use is deemed appropriate, the remaining footprint of the tendon is preserved, and healing potential will be provided by only REGENETEN. By replacing the invasive take-down and repair technique with isolated REGENETEN use, this new surgical option will provide access to an accelerated rehabilitation program which results in lower pain and a faster return of function (McIntyre et al., 2021). The ability to increase function and decrease pain also influences overall physical and mental health as measured by the VR-12 (McIntyre et al., 2021).

For FTRCT, Using REGENETEN as an adjunct to the suture anchor repair has been shown to decrease the risk of retear following repair, therefore, minimizing the number of surgical interventions required for rotator cuff pathology (Ferreira Barros, 2022; Iban, 2022).

The introduction of REGENETEN, satisfies the following unmet needs:

- The need for a surgical solution for rotator cuff disease, that better preserves the natural anatomy of the shoulder joint to provide better patient recovery, including faster relief from pain, improvements in function, and return to an independent and active lifestyle
- The need for a technology that can facilitate the formation of new tendon-like tissue and demonstrate a reduced risk of postoperative re-tears.
- The need for a technology that can result in a faster recovery and low risk of re-tearing. This can be expected to promote earlier return to work, improve productivity, and reduce workers compensation payouts, resulting in a wider societal benefit

Specified restrictions for funding

Please add one or more items, with specified restriction for funding, for each Population / Intervention:

Proposed item: AAAAA

Is the proposed item restricted?
No - unrestricted

Provide a short description of the restriction:
-

Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:
-

Proposed price of supply:
[redacted]

Indicate the overall cost per patient of providing the proposed health technology:
[redacted]

Provide details and explain:
As per cost breakdown attachment, overall cost per patient (inclusive of hospital rebate - 75%) is
[redacted]

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payment):
REGENETEN is currently self-funded by patients (in the private setting). In Queensland, patients may receive funding via workers compensation. However, in all other states, this is assessed on a case-by-case basis.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?
Superior

Please state what the overall claim is, and provide a rationale:
As per 1593 Ratified PICO, the overall clinical claim is that REGENETEN is associated with superior health outcomes for patients with RCTs through improved efficacy and at least non-inferior safety, if not superior safety, in comparison to treatment with standard surgical repair.

The rationale for this claim are the results from the REGENETEN clinical trial program which demonstrated that patients in the REGENETEN arm experienced significantly lower re-tear rates, significantly lower failure rate at the musculotendinous junction, loser post-operative fatty infiltration, no difference in complications between groups, improvement in function and pain scores (Constant-Murley Shoulder Score and VAS pain score assessments) compared to the control group (standard surgical repair) (Ferreira Barros, 2022; Iban, 2022).

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
The applied incidence of 131 of 100,000 rotator cuff repairs from a population-based study in Finland (Paloneva et al., 2015)

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):
[redacted]

Year 2 estimated uptake (%):
[redacted]

Year 3 estimated uptake (%):
[redacted]

Year 4 estimated uptake (%):
[redacted]

Estimate the number of patients who will utilise the proposed technology for the first full year:
[redacted]

Optionally, provide details:
As per ratified PICO 1593, a market share approach is inappropriate as item 48960 (which was considered by PASC as the most applicable item given it refers to arthroscopic repair) also includes shoulder reconstruction, resection, and replacement services, therefore, using this approach would likely misrepresent (overestimate) the eligible population for BCI in rotator cuff surgical repair.

Therefore, an epidemiological approach estimating the expected utilisation of BCI in rotator cuff surgical repair in Australia over the next four years will be used to estimate utilisation. The applied incidence of 131 of 100,000 rotator cuff repairs from a population-based study in Finland (Paloneva et al., 2015) to the current adult Australian population estimates from the Australian Bureau of Statistics (ABS) (3222.0 Series B (Australian Bureau of Statistics, 2018)). As per the pivotal trial by Dr Ruiz Iban (Ruiz Iban & Smith & Nephew, 2022), the inclusion criteria consisted of patients aged >18, this has been accounted for in parameter B of Table 1.

The Applicant then derived the proportion of procedures that would be performed in the private setting using the estimate that 45.1% of the Australian population are privately insured in December 2022 (Australia Prudential Regulation Authority, 2022); a total of 12,550 rotator cuff repairs would be performed in Year 1 (2024). The Applicant has assumed a [redacted]% uptake rate in year 1, which would increase linearly to [redacted]% in year 4 (2027). Uptake rate estimates have been based on assumption, and not evidence, however, will be validated by primary research with Australian Surgeons prior to the submission of an ADAR.

There are no apparent constraints in the health care system that would impact on uptake.

As per 1593 Ratified PICO, the Applicant expects the risk of leakage to be low. It is acknowledged that ESC was previously concerned about leakage, prompting MSAC to suggest in the 1593 PSD "the relevant authorities may wish to consider introduction of measures to implement a once-only per shoulder restriction" (PSD, p5).

The Applicant has acknowledged ESC and MSACs leakage concern and acknowledges notes in the I.S.Mu.L.T (Italian Society of Muscles, Tendons and Ligaments Rotator Cuff Tear Guidelines that, while diagnostic accuracy of MRI for detection of FTRCTs is excellent, it is more limited for PTRCTs (Oliva et al., 2015). However, the applicant would like to state that this is not the current standard of care for patients who are not symptomatic or who have not yet undertaken conservative management to be referred to an orthopaedic surgeon. It is unlikely that patients without symptoms would elect to undergo surgery. In the event that symptoms fail to improve following a minimum of 3 months of conservative treatment, or where a tear has 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 is then indicated (Brun, 2012).

A REGENETEN registry (Amplitude) is being undertaken to capture data to demonstrate the real-world value of the device. Data has been captured from the United Kingdom and Hong Kong, with Australian patients to be included as of April 2023. The intention of this registry is to further support and evaluate the health economic impact of REGENETEN and evaluate the PROMs to demonstrate how REGENETEN is improving outcomes for patients. Furthermore, data from this registry will be used to support utilisation estimates and demonstrate the 'once per shoulder' frequency of REGENETEN and to demonstrate the low leakage risk. The Applicant is willing to work with the relevant authorities to aid in ensuring a 'once-per shoulder' restriction as was recommended by MSAC in the ratified PSD.

Will the technology be needed more than once per patient?
No, once only

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

- Australian Orthopeadic Association (AOA)
- Shoulder and Elbow Society of Australia (SESA)

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:
n/a

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

- Queensland Workcover

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

- Australian Orthopeadic Association (AOA)
- Shoulder and Elbow Society of Australia (SESA)

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?
Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?
Yes

340095 – REGENETEN Arthroscopic Bioinductive Implant

340096 – REGENETEN Mini-open implant

384118 – Bioinductive Implant with Arthroscopic Delivery System - Multi-purpose surgical mesh, collagen

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

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?
No

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?
No

Is the therapeutic good in the process of being considered by the TGA?
No

Please provide details of when you intend to lodge an ARTG inclusion application, or provide a rationale if you do not intend to lodge an ARTG inclusion application:
Our device is already TGA listed.