MSAC Application 1593.2

Bioinductive implant for the repair of rotator cuff tear

Application or referral for other medical service or health technology

MSAC application number:
1593.2

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., 2015).

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:
Prescribed 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.

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 this application are patients who receive a REGENETEN™ bioinductive collagen implant (BCI) (Hereafter referred to as 'REGENETEN'), in addition to a mechanical surgical repair (full-thickness tears) of clinically diagnosed symptomatic rotator cuff tears. Specifically, patients with identified symptomatic full-thickness rotator cuff tear (FTRCT) where there is no substantial loss of tissue who have failed at least three months of conservative medical management (CMM).

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:

Standard surgical treatment for symptomatic FTRCTs is performed arthroscopically or as 'mini-open' surgery and involves reattaching the muscle to the bone using standard sutures and anchors.

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 or adjunct to standard arthroscopic surgical repair (sutures and anchors) 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.

Using REGENETEN as an adjunct to the suture anchor repair for FTRCT has been shown to decrease the risk of retear following repair, therefore, minimising the number of surgical interventions required for rotator cuff pathology (Ruiz Iban et al. 2024).

The introduction of REGENETEN, satisfies the following unmet needs:

- The need for a technology that can facilitate the formation of new tendon-like tissue and demonstrate a reduced risk of postoperative re-tears.
- Although radiographic re-tears is a surrogate outcome there is a large body of evidence which demonstrates it as having a level of clinical relevance.
- Systematic literature reviews with meta-analysis have shown statistically significant better ASES and CM scores in patients with healed tendon than those with retears within a wide follow-up range (1.5-10 years). This observation is highlighted in AAOS clinical practice guidelines which states that “healed rotator cuff repairs show improved patient reported outcomes to physical therapy and unhealed rotator cuff repairs”. When considering individual studies CM and ASES scores were consistently statistically significant better for patients with healed tendons when follow-up was greater than 2 years but comparable when less than 2 years. These observations are clearly highlighted in the findings of Kluger et al 2011 which reported no significant difference in patient reported outcomes between atraumatic re-tears and healed tears in the short term (3-6 months) but significant differences at 2 and 7 year follow-ups. The authors concluded “The parameters “recurrent tear” as well as “healed tendon” at 6 months postoperatively were predictors for the clinical outcomes at 7 years”. Therefore, the observations by Ruiz-Iban et al (2023) in not observing functional differences between patients who experienced a re-tear and did not at 1 year and the observations of significant differences at 2 years is not a surprise.
- Further to this, the study conducted by Ruiz-Iban et al is powered based on re-tear as an outcome. Patients who avoid a re-tear would not be expected to have differences in functional outcomes, irrespective of their treatment arm. As a large proportion of patients avoided a re-tear in both study arms, the impact of REGENETEN on PROMs masks the benefit of REGENETEN and attention needs to be focused on a patient level and the impact that a failed surgery possess.

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

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, funding is available through workers' compensation, while in other states, coverage is determined on a case-by-case basis. However, approvals are becoming more frequent across various workers' compensation insurers nationwide. Although volumes remain modest, the technology is being recognised more widely, with an emphasis on responsible and appropriate utilisation. It is implemented by specifically trained shoulder surgeons and is increasingly supported by a diverse range of payors, including workers' compensation schemes, public hospitals, and select ex-gratia approvals from private health funds.

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:
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 is the results from the REGENETEN clinical trial program which demonstrated that FTRCT 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. (Ruiz Iban et al. 2024).

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.

A potential decrease in hospital resources (operative) if the application of REGENETEN results in fewer patients requiring subsequent surgical revision, due to clinical failure (I.e. re-tear) of the primary rotator cuff tear procedure. Bokor et al. (1, 2) reported no tear progression or re-tears were observed during 24-month follow-up. However, in a population with advanced FTRCT disease (large and massive tears), two patients (9%) had clinical failure, with one requiring revision surgery with reverse shoulder arthroplasty, due to progression of patient's arthritis and further atrophy of rotator cuff (Thon et al 2019 (22)) (see efficacy results for REGENETEN)

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).

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 Orthopaedic 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.