Australian Government

Department of Health

Application Forms

Arthroscopic injection of a bioadhesive hydrogel implant (JointRep™), in conjunction with microfracture, for treatment of osteochondral defects of the knee

(New and Amended Requests 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 in order 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):
Corporation name: Device Technologies Australia
ABN: 40 058 091 973
Business trading name: Device Technologies Australia

Primary contact name: REDACTED

Primary contact numbers
Business: Redacted
Mobile: Redacted
Email: Redacted

Alternative contact name: REDACTED

Alternative contact numbers
Business: Redacted
Mobile: Redacted
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

Arthroscopic injection of a bioadhesive hydrogel implant (JointRep™) in conjunction with microfracture for treatment of osteochondral defects of the knee.

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)

Moderate to severe symptomatic focal osteochondral defects (OCDs) that have not been successfully treated with conservative therapy. Symptoms can include pain, swelling, stiffness, locking, clicking or crepitus. Hyaline cartilage has no vasculature and has a very limited capacity for self-repair. Therefore, if the lesion is left untreated there is likely progression to osteoarthritis and possible total knee replacement in later life.

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 JointRep™ device is an injectable sterile, non-pyrogenic, thermo-gel implant with a glucosamine polysaccharide formulation that is used following bone-marrow stimulating arthroscopic surgery (microfracture). It is designed to fill and resurface cartilage defects. JointRep™ forms a scaffold in situ that provides support for progenitor cells. The microfracture arthroscopic surgery is an articular repair technique which requires the creation of tiny fractures in the underlying bone that allows entry of bone marrow cells into the vicinity of the defect. Normally an extended period of non-weightbearing (approximately 6-8 weeks) is required following surgery to protect the clot formed over the articular cartilage, however if JointRep™ is implanted during the microfracture procedure, post-operative weightbearing as tolerated (WBAT) is possible within 24-48 hours of the procedure.

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

☐ Yes
☒ No

Microfracture and chondroplasty techniques are already included on the MBS. The current application is being made as a response to a referral by the Prostheses List Advisory Committee (PLAC) to MSAC as part of a wider assessment of cartilage repair procedures.

(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?

The implantation of JointRep™ is included in the procedures included in MBS item numbers 49559 and 49562.

(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:

While an amendment to an existing item number is not being sought, the relevant item numbers for the microfracture and/or chondroplasty procedures include MBS 49559 and MBS 49562.

(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):

Insert description of 'other' amendment here

(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:

Insert description of other public funding mechanism here

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)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☐ Assists in establishing a diagnosis in symptomatic patients
iii. ☐ Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☐ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

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?

Not applicable

☐ Yes
☐ No

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

Not applicable

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

Not applicable

☐ Yes (please provide PBAC submission item number below)
☐ No

Insert PBAC submission item number here

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

Not applicable

Trade name: Insert trade name here
Generic name: Insert generic name here

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

☐ Yes
☒ No

The JointRep™ device has been included on the July 2019 Prostheses List following a recommendation for listing by the PLAC on August 10, 2018 pending ARTG.

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

Billing code(s): DE681
Trade name of prostheses: JointRep™
Clinical name of prostheses: Thermogelling bioscaffold
Other device components delivered as part of the service:

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

Please see Question 11.

☐ Yes
☐ No

(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

This application only pertains to JointRep™, however there Cargel is an earlier generation device that requires mixing with the patient's blood prior to implantation. Cargel is currently included on the Prostheses List

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):
The sponsor is Smith and Nephew Pty Ltd and the manufacturer is Piramal Healthcare Canada Ltd, Bio-Orthopaedics Division

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

Single use consumables: None
Multi-use consumables: None

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: Medical Device
Manufacturer's name: Oligo Medic
Sponsor's name: Device Technologies Australia

(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: 316444
TGA approved indication(s), if applicable: JointRep injectable implant is indicated for implantation for the treatment of cartilage defects, for reducing joint pain and improving joint functions and patient activities
TGA approved purpose(s), if applicable: JointRep™ injectable implant is indicated for implantation for the treatment of isolated cartilage defects grade III and IV (ICRS/Outerbridge scores) of the knee joint in combination with microfracture surgery. Use of the implant is not appropriate in the presence of more generalised degeneration, meniscal deficiency or established osteoarthritis

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: Insert date of submission here
Estimated date by which TGA approval can be expected: Insert estimated date here
TGA Application ID: Insert TGA Application ID here
TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here
TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

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: Insert date of submission here
Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)
Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

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.	Controlled trial of microfracture and microfracture plus hydrogel scaffolds	Pipino G et al *'Microfractures and hydrogel scaffolds in the treatment of osteochondral knee defects: A clinical and histological evaluation'* J Clin Orthop Trauma (2018) https://doi.org/10.1016/j.jcot.2018.03.001	A controlled trial of microfracture and microfracture and JointRep™. 46 patients were consecutively treated with microfracture and JointRep™. The results were compared with a consecutive matched controlled group of 23 patients and all were followed for 2 years. A parallel and separate invitro histological study was also conducted.	www.sciencedirect.com/science/article/pii/S0976566217304769	March 3 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.	Blinded Pragmatic RCT	Microfracture and AMIC in Osteochondral Lesions of the Talus	RCT comparing microfracture of the talus with microfracture and JointRep™ of the talus in 1650 patients Outcome measures: VAS pain during ADL VAS pain during exercise AOFAS hindfoot score Roles and Maudsley scores	Insert website link	2021 approx.
2.	RCT	FDA abridged 510k study	150 patients randomised to either microfracture of JointRep™ and microfracture. Outcomes will include MRI imaging and arthroscopic examination	Insert website link	2022
3.	Pilot	Not available	10 patient safety and efficacy study of JointRep™ in the first metatarsal phalangeal joint	Insert website link	Q2 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):**

    Australian Orthopaedic Association

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

    Australian Orthopaedic Association

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

    Not applicable

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

    Smith and Nephew Pty Ltd

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

    Name of expert 2: 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), INDICATION, 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:

Articular cartilage is a connective tissue that covers articulating surfaces of weight-bearing bones. These include the distal surface of the femoral condyles, the posterior surface of the patella and medial and lateral surfaces of the tibial plateau of the knee, the acetabular fossa of the hip joint, the superior surface of the talar and distal surface of the tibia in the ankle.

Articular cartilage is composed of hyaline cartilage which consists of a dense extracellular matrix with a distribution of chondrocyte (cartilage) cells. Articular cartilage performs a crucial biomechanical function. Cartilage tissue decreases friction and distributes load so that highly complex joints such as the knee and the ankle can progress through a variety of range of motion planes, accelerate and decelerate movement while weightbearing. This application pertains to the knee.

Injuries to articular cartilage can be problematic as articular cartilage does not have vasculature and nutrition is received by diffusion from the synovial fluid and therefore articular cartilage lacks the ability to repair itself.

Sporting injuries are a common cause of damage to articular cartilage. Damage to the articular cartilage may also be a result of arthritis or through a disease process such as osteochondritis dissecans (OCD). Cartilage damage may also be a secondary injury from joint instability or abnormal loading of joint surfaces secondary to other musculoskeletal abnormalities[1]. Loss of articular cartilage is commonly referred to as a 'chondral defect'.

Patients with chondral defects, particularly those that are deeper and larger, suffer pain and loss of function. Symptoms include pain, joint infusion, joint locking or instability. These symptoms in weight bearing joints can have a significant impact on the ability to participate in work and leisure activities and have the ability to significantly reduce quality of life. Functional impairments can be similar to patients who are candidates for knee replacement surgery[2]. As chondral defects typically occur in younger patients, productivity losses to society may be significant.

Chondral Defects can be classified using the Outerbridge classification system.

Grade	Definition
0	Normal
I	Cartilage with softening and swelling
II	A partial-thickness defect with fissures on the surface that do not reach the subchondral bone or exceed 1.5cm in diameter
III	Fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm
IV	Exposed subchondral bone

[1] Meyerkort D *One-stage vs two-stage cartilage repair: a current review.* Orthop. Res. Rev. 2010: 2, 1-12

[2] Heir S *Focal cartilage defects in the knee impair quality of life as much as severe osteoarthritis: a comparison of knee injury and osteoarthritis outcome score in 4 patient categories scheduled for knee surgery.'* AM J Sports Med. 2010 Feb; 38 (2) 231-7

It is difficult to quantify the number of Australians who may have a chondral defect. Repair of chondral defects most commonly occurs in knee joints and this application will focus primarily on this group. It is estimated that between 5-11% of the general population may have a chondral defect of the knee[3] Widuchowski et al [4] studied over 25,000 arthroscopies and determined that 7% of patients under 40 and 9% of those under 50 were candidates for chondral repair. These patients had one to three localised grade III or IV lesions. The condition is often seen in combination with other internal derangements of the knee such as ligament damage and a mal-tracking patella.

Chondroplasty, microfracture and mosaicplasty are all procedures performed in Australia to repair chondral defects of the knee. The number of these procedures performed in Australia is an indication of the burden the condition imposes upon the health system.

Item numbers MBS 49559, 49562, 49563 and 49561 encompass these procedures. Please see Table 1 which lists the number of claims for financial year 2017-2018 for these item numbers[5].

Table 1

MBS Item	No of claims 2017-2018
MBS 49559 KNEE, arthroscopic surgery of, involving chondroplasty requiring multiple drilling or carbon fibre (or similar) implant; including any associated debridement or osteoplasty - not associated with any other arthroscopic procedure of the knee region (Anes.) (Assist.) Fee: $408.70	74
MBS 49562 KNEE, ARTHROSCOPIC SURGERY OF, involving 1 or more of: partial or total meniscectomy, removal of loose body or lateral release; where the procedure includes chondroplasty requiring multiple drilling or carbon fibre (or similar) implant and associated debridement or osteoplasty - not associated with any other arthroscopic procedure of the knee region (Anaes.) (Assist.) **Fee:** $735.50	3,207
MBS 49563 KNEE, arthroscopic surgery of, involving 1 or more of: meniscus repair; osteochondral graft; or chondral graft (excluding autologous chondrocyte implantation or matrix-induced autologous chondrocyte implantation) – not associated with any other arthroscopic procedure of the knee region (Anaes.) (Assist.)	1,669

[3] Bekkers J *Cartilage Repair in Football (Soccer) Athletes What Evidence Leads to Which Treatment? A Critical Review of the Literature.* Cartilage 2012; 31(1 Suppl):43S-49S

[4] Widuchowski, W., Widuchowski, J. & Trzaska, T. *Articular cartilage defects: study of 25,124 knee arthroscopies*. Knee (2007) 14, 177–82.

[5] www.medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp

MBS Item	No of claims 2017-2018
Fee: $796.70	
MBS 49561 KNEE, ARTHROSCOPIC SURGERY OF, involving 1 or more of: partial or total meniscectomy, removal of loose body or lateral release: where the procedure includes associated debridement, osteoplasty or chondroplasty – not associated with any other arthroscopic procedure of the knee region (Anaes.) (Assist.) Fee: $674.00	32,419

Australian Institute of Health and Welfare statistics[6] show the following procedure numbers for 2016-2017.

Table 2

Code	Procedure	Number of Procedures
49558-01	Arthroscopic chondroplasty of knee	5,937
49561-02	Arthroscopic removal of loose body of knee with debridement, osteoplasty or chondroplasty	5,103
49562-02	Arthroscopic removal of loose body of knee with chondroplasty and multiple drilling or implant	333
49561-00	Arthroscopic lateral release of knee with debridement, osteoplasty or chondroplasty	1,793
49562-00	Arthroscopic lateral release of knee with chondroplasty and multiple drilling or implant	165
49561-01	Arthroscopic meniscectomy of knee with debridement, osteoplasty or chondroplasty	38,251
49562-01	Arthroscopic meniscectomy of knee with chondroplasty and multiple drilling or implant	821

Symptomatic articular cartilage lesions have a strong correlation with osteoarthritis (OA) in later life. It is estimated that 68% of individuals over 55 years of age will have evidence of OA upon imaging with focal cartilage lesions. Knee arthroplasty is the only option for patients when symptoms are unable to be managed by conservative means[7]

[6] Procedures and healthcare interventions (ACHI 9th edition), Australia 2016-17, AIHW National Morbidity Database

[7] Willers C et al *Articular Cartilage Repair: procedures versus products.* Expert Rev. Med. Devices 4(3), 373–392 (2007)

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:

JointRep™ is intended for use in association with microfracture procedures for treatment of symptomatic focal osteochondral defects classified as Grade III or IV. Patients with smaller lesions have better clinical improvement than patients with larger lesions, therefore patients with larger lesions are more likely to require intervention. [8] Although patients with OA were included in the Pipino study listed above, this is not the intended population in an Australian context.

Patients with traumatic focal lesions are likely to be younger and to have suffered a traumatic incident. As cartilage has no nerve supply, defects may not always be painful, and some patients may present at a later stage after the defect has progressed and associated symptoms develop. A recent review of arthroscopy findings observed 53,569 articular cartilage lesions in 19,827 patients (62.9%)[9], demonstrating that cartilage defects are often an incidental finding in patients presenting with knee problems.

Symptoms of focal chondral lesions include pain, stiffness, swelling, clicking or locking of the knee in one position and lack of range of motion.

Investigations

Physical examination of the knee joint may identify characteristics that may be associated with focal chondral defects. These may include, joint laxity, mal-tracking patella, mal-alignment, ligament instability or overload on the medial and lateral compartments.

Imaging may include, x-rays, CT scans and MRIs with MRI likely to be the most sensitive to the detection and grading of focal chondral defects.

Treatment

First line therapy is conservative and non-invasive, particularly when symptoms are not severe and may include rest, non-steroidal anti-inflammatories (NSAIDs) and physiotherapy. More severe symptoms may be treated with corticosteroids, visco-supplementation (injection of a lubrication fluid into the knee joint), steroidal injections and an unloading brace. These measures are intended to treat the symptoms of the defect but will not have any healing effect on the defect itself.

When all conservative measures have been tried and have failed to produce a satisfactory outcome, surgery is likely to be considered, particularly in younger patients. There are a variety of arthroscopic knee procedures that may be considered. These include lavage (injection of saline and removal of loose fragments through a cannula) or debridement, where the intention is to remove any loose flaps of cartilage or chondral fragments which may be mechanically blocking free movement of the joint. Arthroscopy is also an opportunity to visualise and definitively diagnose the defect. These techniques are often performed together, but similarly to conservative management do not promote healing of the chondral defect.

Should these interventions all prove unsuccessful in reducing symptoms, then chondral repair procedures are likely to be considered. These include mosaicplasty, microfracture and autologous chondrocyte implantation. Mosaicplasty and microfracture procedures are included on the MBS. JointRep™ is intended to be used during microfracture procedures.

[8] Erggelet C, Vavken P, *Microfracture for the treatment of cartilage defects in the knee joint – A golden standard?*' Jnl Clin Orthop and trauma 7 (2016) 145-152

[9] Curl W et al *Cartilage Injuries: A Review of 31,516 Knee Arthroscopies.* Jnl Arthosc Rel Surg. 1997; 13(4), 456-460

Referral Pathway

Patients will present to either a General Practitioner (GP) or an emergency room. Patients typically will report a history of trauma, such as a sporting injury and will present with pain and swelling. Some patients may not be able to identify a precipitating event and will present with a more gradual onset of symptoms. If symptoms are mild conservative treatment may be trialled such as NSAIDs and physiotherapy.

If symptoms are unresolved then referral will be made to either an orthopaedic surgeon or possibly a sports physician. Imaging may be conducted prior to or following attendance at an orthopaedic surgeon/sports physician.

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):

As noted above, the most definitive diagnosis is likely to be made from MRI imaging or possibly by arthroscopy. Occasionally a lesion may be identified incidentally on MRI or arthroscope during investigations of other pathologies. During diagnostic arthroscopy, lavage or debridement may be performed to remove loose cartilage.

If symptoms continue despite first line therapies, then surgical repair of the defect will be considered. At this point microfracture with JointRep™ may be performed.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

JointRep™ is implanted during the microfracture procedure. The surgeon uses arthroscopy to visualise the defect. After the cartilage damage is assessed, any unstable cartilage is removed from the exposed bone. The surrounding rim of remaining cartilage is also checked for loose or marginally attached cartilage. This loose cartilage is also removed so that there is a stable edge of cartilage surrounding the defect.

Multiple holes, or microfractures are then drilled into the exposed bone 3-4mm apart. Bone marrow cells and blood from the holes combine to form a clot that covers the lesion.

JointRep™ is mixed intraoperatively prior to delivery and is injected arthroscopically into the defect immediately following the microfracture procedure. The solution rapidly solidifies after being heated by the body temperature. The resulting matrix provides a scaffold for chondrocyte proliferation. The biomechanical properties of JointRep™ allow for weightbearing within 24-48 hours of surgery.

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

JointRep™ is a registered trademark of Oligo Medic Inc and covers injectable gels for use in the treatment and reparation of human articular joints. JointRep™ is distinguished from other products in that there is no necessity to mix the product with blood and weightbearing is expedited following its use.

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?

JointRep™ is intended for use in patients with Grade III or IV focal chondral defects, usually of a traumatic aetiology.

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):

JointRep™ is simple to administer and so all orthopaedic surgeons will be able to deliver the service. Availability of trained doctors is not anticipated to be a barrier to access. As JointRep™ is an additional cost to the microfracture procedure, its use may be constrained in the public sector. As JointRep™ is listed on the Prostheses List, this is not a barrier to access in the private sector.

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:

A physiotherapist may attend the patient immediately following surgery.

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

The service is delivered by orthopaedic surgeons.

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

The service cannot be delegated.

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

The service must be delivered by a doctor who is qualified to perform orthopaedic surgery in Australia

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 service must be provided by a Fellow of the Royal Australasian College of Surgeons who has completed the Orthopaedic Surgery Surgical Education Training program delivered by the Australian Orthopaedic Association or the New Zealand Orthopaedic Association, or else who is otherwise qualified to practice Orthopaedic Surgery in Australia.

There is no specific training required to use JointRep™

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

- ☒ Inpatient private hospital
- ☒ Inpatient public hospital
- ☐ Outpatient clinic
- ☐ Emergency Department
- ☐ Consulting rooms
- ☒ Day surgery centre
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

Specify further details here

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

The microfracture procedure with JointRep™ is generally an inpatient procedure,and can therefore be performed in a public or private hospital that performs arthroscopic procedures.

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):

The comparator is microfracture without the addition of JointRep™. The clinical management of patients who receive JointRep™ will essentially be the same as those who do not receive JointRep™ and this has been described earlier. The main difference is that patients receiving JointRep™ will be able to weight bear within 24-48 hours whereas microfracture without JointRep™ requires a lengthy period of non-weightbearing (6-8 weeks).

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

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

Microfracture Item Numbers

MBS 49559

KNEE, arthroscopic surgery of, involving chondroplasty requiring multiple drilling or carbon fibre (or similar) implant; including any associated debridement or oestoplasty - not associated with any other arthroscopic procedure of the knee region (Anes.) (Assist.)

Fee: $408.70

MBS 49562

KNEE, ARTHROSCOPIC SURGERY OF, involving 1 or more of: partial or total meniscectomy, removal of loose body or lateral release; where the procedure includes chondroplasty requiring multiple drilling or carbon fibre (or similar) implant and associated debridement or osteoplasty - not associated with any other arthroscopic procedure of the knee region

(Anaes.) (Assist.)

Fee: $735.50

40. Define and summarise the current clinical management pathways 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):

Patients treated with microfracture and JointRep™ will require an intensive rehabilitation program. This is required so that the complex musculature supporting the knee is strengthened, patella-femoral alignment is correct, so that a mal-tracking patella is avoided, and the patient has sufficient endurance to return to their normal activities.

Should the repair fail, or symptoms recur, a second surgical repair may be attempted with a similar knee rehabilitation program. As patients age, some may require a knee replacement. This may be a consequence of the original cartilage defect or may be a result of unrelated osteoarthritic changes. Please see the attached clinical pathway.

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

JointRep™ will be in addition to the microfracture procedure.

☐ Yes
☐ No

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

Not applicable.

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):

The clinical pathway will be very similar, however the biomechanical properties of JointRep™ allow for much-sooner post-operative weightbearing. This is likely to result in a shortened rehabilitation program and a more rapid return to normal activities than microfracture alone. Typically, microfracture patients are non-weight bearing for at least six weeks[10]

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):

JointRep™ and microfracture is likely to be superior to microfracture alone in terms pain, stiffness and function at 3 years.

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:

Serious Adverse Events

Clinical Effectiveness Outcomes:

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores

[10] Wilk KE, Macrina LC and Reinold MM, *Rehabilitation following Microfracture of the Knee'* Cartilage. 2010 Apr; 1(2) 96-107

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

It is difficult to estimate the overall prevalence of osteochondral lesions that would be eligible for JointRep™. Most studies of prevalence of articular defects analyse results of arthroscopic investigations[11],[12]. However as many of these lesions are not symptomatic, they may not be candidates for repair. Since JointRep™ is intended for use in association with microfracture, it is perhaps more useful to estimate the proposed population by examining the number of microfracture procedures conducted each year in Australia.

It is difficult to estimate the total number of microfracture procedures that take place in Australia. This is due to definitional issues where microfracture may be considered a 'chondroplasty' procedure. Experience in the field leads the sponsor to believe that there is substantial cross-over between claimed MBS item numbers that describe knee arthroscopic procedures and it is difficult to define precisely how many 'chondroplasty' claims may incorporate a microfracture procedure.

AIHW statistics referenced in Question 23 report 1,319 procedures that include 'multiple drilling'. This is possibly an underestimate of the number of microfracture procedures. Procedures which include arthroscopic chondroplasty total 52,403 which is clearly an overestimate of the number of microfracture procedures.

If we look at Medicare statistics, the combined total claims for Items 49559 and 49562 in financial year 2017/2018 was 3,281. This appears to be a more realistic number but does not include procedures carried out on public patients. Since JointRep™ is an additional cost to the procedure it is more likely that JointRep™ will be an option for private patients where a private health insurance benefit will be available for the device.

An estimate of the likely eligible population is 3,281.

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

Once in any one year per knee.

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

One year.

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

While there may be over 3000 eligible patients, it is likely that only a fraction of these patients would receive JointRep™, particularly during the introductory years of the technology. The sponsor has had experience in supplying an early generation bioscaffold device. This device was used 10-20 times per month. JointRep™ is likely to be more attractive to surgeons as it does not require mixing with blood and full weight-bearing can withing a day or two of surgery.

So as to not underestimate the cost impact of using JointRep™, it is assumed that JointRep™ will enter the market with 25 uses per month for a total of 300 in the first year. This is 9.1 percent of the eligible population.

[11]Widuchowski et al *'Articular cartilage defects: study of 25, 124 knee arthroscopies'* Knee 20017; Jun; 14(3): 177-82.

[12] Flanigan DC et al *'Prevalence of chondral defects in athlete's knees: a systematic review'* Med Sci Sports Exerc. 2010 Oct; 42 (10): 1795-801

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:

If JointRep™ is available and included on the Prostheses List, then it is estimated that the proportion of the eligible population will increase by 5% each year and plateau at 30% of the eligible population over time. Please see Table 1 for utilisation projections.

Table 1

	Description	Source	2021	2022	2023
A	**Eligible Population**	**Assume 1.6% population growth with static PHI membership rates with an eligible population of 3,333 in 2020**	**3386**	**3440**	**3493**
B	**Percentage of Eligible Population**	**Assume additional 5.0% of population each year**	**14.1%**	**19.1%**	**24.1%**
C	**Number of Microfracture and JointRep™ procedures**	**A*B**	**477**	**657**	**841**

PART 8 – COST INFORMATION

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

JointRep™, when approved, will attract a benefit of $6022. It is implanted during a microfracture procedure.

Service	Item	Fee/Cost	Medicare Benefit	PHI Benefit	Cost
Anaesthesia	**MBS 17610** **MBS 21382** **MBS 23063**	**$43.00** **$79.20** **$118.80**	**$32.25** **$59.40** **$89.10**	**$10.75** **$19.80** **$29.70**	**$43.00** **$79.20** **$118.80**
Microfracture Procedure	**MBS 49562**	**$735.50**	**$551.65**	**$183.85**	**$735.50**
Assistant	**MBS 51303**	**$147.10**	**$110.35**	**$36.75**	**$147.10**
Hospital	**Assume AR-DRG I24B** (minus medical costs)	**$,3148.00**		**$3,148.00**	**$3,148.00**
JointRep™	**PL Rebate**	**$6,022**		**$6,022**	**$6,022**
Total			**$842.75**	**$9,450.85**	**$10,293.60**

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

The microfracture procedure when performed in isolation takes 45 minutes to perform. JointRep™ is delivered by a simple injection through the arthroscope. The additional time added to the procedure is negligible. It is often the case that other arthroscopic repairs such as a lateral release, ligament repair or removal of loose bodies may be performed at the same time, so a conservative time of 1.5 hours is assumed.

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.

Public funding is not being sought through the MBS. The current MBS item numbers adequately describe the microfracture procedure.

Category (insert proposed category number here) – (insert proposed category description here)
Proposed item descriptor: insert proposed item descriptor here Fee: $(insert proposed fee here)