MSAC Application 1773

Autologous chondrocyte implantation for symptomatic articular cartilage defects greater than 2cm^2 of the knee

Application for MBS eligible service or health technology

MSAC Application Number:
1773

Application title:
Autologous Chondrocyte Implantation for symptomatic articular cartilage defects greater than 2cm^2 of the knee

Submitting organisation:
WURLEY GROUP PTY LTD

Submitting organisation ABN:
13100392827

Application description

Succinct description of the medical condition/s:
Symptomatic loss of articular (joint) cartilage (chondral defect) of the knee. Symptoms include pain, swelling, joint stiffness and joint clicking or locking. Hyaline cartilage has no blood vessels and therefore has limited potential for self-repair. Therefore, if left untreated, cartilage injury often progresses to osteoarthritis in the affected joint

Succinct description of the service or health technology:
Autologous Chondrocyte Implantation (ACI) aims to stimulate new cartilage production by encouraging the growth of cartilage cells (chondrocytes), which are responsible for production and maintenance of cartilage tissue, that are implanted in areas of damaged cartilage. Healthy articular cartilage is harvested via a small incision from a non-weight bearing location within the joint. The cartilage biopsy is sent to a laboratory where the chondrocytes are isolated from the cartilage and expanded in vitro (in a test tube or dish). Approximately 5 weeks after biopsy collection, the cultured chondrocytes are seeded onto a supporting collagen scaffold trimmed to the appropriate size. The scaffold/chondrocyte implant is fixed in place at the injury site using fibrin glue to keep the repair in place during normal range of motion

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?
Consultant

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

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?
Yes

Which list/schedule will the other health technologies be listed on?
Prescribed List

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?
New

Please select any relevant MBS items.

MBS item number	Selected reason type
49576	Other

What is the type of service or health technology?
Therapeutic

PICO Set

Autologous Chondrocyte Implantation for symptomatic articular cartilage defects of the knee

Population

Describe the population in which the proposed health technology is intended to be used:
Patients with symptomatic articular cartilage defects greater than 2cm^2 of the knee.

Patient characteristics include symptomatic loss of articular cartilage (chondral defect) of the knee. Symptoms include pain, swelling, joint stiffness and joint clicking or locking. Hyaline cartilage has no blood vessels and therefore has limited potential for self-repair. Therefore, if left untreated, cartilage injury often progresses to osteoarthritis in the affected joint and potentially may require joint replacement surgery.

ACI is indicated for use in treatment of symptomatic cartilage damage caused by trauma, wear or degradation. Patient characteristics to be eligible for ACI treatment are as follows:

- aged between 18 and 55 years
- have focal chondral defects greater than or equal to 2cm^2 and less than 20cm^2 in an otherwise normal joint
- chondral defects associated with chondromalacia patella or osteochondritis dissecans are ICRS grade 3 or 4
- defects should not be associated with rheumatoid and other inflammatory arthritic conditions.
- should not have unstable or mal-aligned joints unless being concurrently corrected.

Search and select the most applicable Medical condition terminology (SNOMED CT):
Defect of articular cartilage

Intervention

Name of the proposed health technology:
Orthocell's Autologous Chondrocyte Implantation (Ortho-ACI™)

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 includes identifying health care resources that are needed to be delivered at the same time as the comparator service:
The main alternative method of repair is microfracture (MF) in which small holes are drilled through the surface of the bone in the area of damaged cartilage. This allows bleeding from the bone marrow, and the blood carries stem cells into the area where the damaged cartilage has been debrided. These cells stimulate the growth of fibrocartilage, composed of

type I collagen. This is regarded as being inferior to hyaline cartilage, being less hardwearing and not expected to last as long.

MF can be done arthroscopically (i.e. without opening the knee joint) and could be done at the same time as washing out a knee joint and stabilising loose tissue (debridement and lavage).

Resources: In the SUMMIT study all patients underwent arthroscopy at baseline to examine their cartilage lesion and surrounding tissues. A small biopsy of cartilage (≈ 200 mg) was taken from a non-weight-bearing healthy area of the femoral condyle in all patients before randomisation, done using an interactive voice response system and computer-generated randomisation system. Those randomised to MF had it immediately. The technique recommended by Steadman et al. (1997) was followed, which included debridement and drilling multiple holes of centres 3–4 mm apart and 4 mm deep in the subchondral bone. Biopsies from patients receiving MF were preserved in case they later required MACI treatment. The MACI group had implantation of the cells 4–8 weeks after biopsy, by mini-arthrotomy. The MACI implant was trimmed to the size of the cartilage defect and implanted securely using a thin layer of fibrin sealant.

Item numbers MBS 49576 and 49503 may be used to describe the microfracture procedure.

MBS 49576 KNEE (Microfracture) repair of chondral lesion of knee, by arthroscopic means, including either or both of the following (if performed):

a. microfracture;
b. microdrilling;

other than a service performed in combination with a service to which another item of this Schedule applies if the service described in the other item is for the purpose of performing chondral or osteochondral grafts (H)

Multiple Operation Rule

(Anaes.) (Assist.)

Fee: $727.50 Benefit: 75% = $545.65

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
In the SUMMIT study, the primary outcomes measure is changes in KOOS for pain and function. The mean change in KOOS-pain from baseline to 2 years was significantly greater in the MACI group than in the MF group (45.5 vs. 35.5, difference between groups 11.76; $p = 0.001$). The change in the KOOS function from baseline to 2 years was also significantly greater in the MACI group (46 vs. 36.1, difference between groups 11.41; $p < 0.001$). Saris et al.(2014) reported that the improvement in the KOOS-pain and pain score in the MACI over MF was observed at 36 weeks and maintained throughout the study period.

Five years after treatment, the improvement in MACI over microfracture in the co-primary endpoint of KOOS pain and function was maintained and was clinically and statistically significant (P = .022). (Brittberg, 2018 SUMMIT study).

After ACI surgery, as with microfracture surgery, all patients in the SUMMIT study were provided with a postoperative rehabilitation program designed to strength the musculature that supports the knee joint, maintain patella femoral tracking and increase range of motion and endurance so that the patient can return to their normal activities.

The introduction of ACI is not intended to change the current clinical pathway following treatment. The clinical management pathway following service delivery of ACI is the same as that for microfracture. It is anticipated that ACI be used only once in a lifetime per lesion.

Microfracture Post-Surgery: Depending on the location of the articular cartilage injury, patients often need to use crutches to keep all weight off the knee for 6 weeks. In some cases, patients can put weight on their knee, but must use a brace to keep the knee straight while walking for 6 weeks. The use of a machine to bend the knee (called a continuous passive motion or CPM machine) is recommended for 6-8 hours per day for 6 weeks after surgery. Return to sports is often delayed for 6 to 9 months after surgery.

If repair by microfracture surgery should fail, then a second repair may be attempted with a similar rehabilitation program. Eventually when patients reach the age of 55 years or older, a knee replacement may be required.

ACI Post-Surgery: Patients will require a brace and crutches. The knee brace will be required for a period of up to three months, depending on the exact location and size of the cartilage defect. The range of motion that will be allowed in the knee brace will also be determined by the exact location and size of the cartilage defect. Generally full weight bearing is restricted for the first six weeks. At 3 weeks the patient can start weight-bearing on the leg and be shifted to a range of motion brace will depend on the location of the lesion in their knee.

At nine weeks from surgery, the patient should be able to walk without crutches and at twelve weeks, the brace can be discarded. Activities requiring standing and walking can commence however, all activities such as squatting, kneeling, stair-climbing and bent knee activity should be delayed until six months from implantation, if possible. Return to sport is not advised within twelve months of implantation.

Proposed MBS items

Proposed Item AAAAA

MBS item number:
49584

Proposed category:
THERAPEUTIC PROCEDURES

Proposed group:
SURGICAL OPERATIONS

Proposed item descriptor:
Harvesting of chondrocytes of knee by arthroscopic means, for preparation of autologous chondrocyte implantation where patients are aged between 15 and 55 years and have a focal chondral defect which is ≥2cm^2.

Proposed MBS fee:
$849.45

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

Please specify any anticipated out of pocket costs:
$212.40

Provide details and explain:
This item number is for the harvesting of chondrocytes. The estimated out of pocket costs are the difference between the benefit and the fee and may be greater if higher gap payments are billed.

Proposed Item BBBBB

MBS item number:
49503

Proposed category:
THERAPEUTIC PROCEDURES

Proposed group:
SURGICAL OPERATIONS

Proposed item descriptor:
Arthrotomy of knee, with autologous chondrocyte implantation in patients who are 15-55 and have a focal chondral defect which is ≥ 2cm^2; other than a service associated with a service to which another item in this Group applies (H) (Anaes.) (Assist.)

Proposed MBS fee:
$536.20

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

Please specify any anticipated out of pocket costs:
$134.05

Provide details and explain:
The out-of-pocket cost is the difference between the fee and benefit. This may be greater if higher gap payments are billed.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
The device is self-funded by patients in the private sector. The device is funded by the hospital in the public sector.

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:
ACI is superior to microfracture.

Evidence of long-term durability of ACI procedures is demonstrated in the follow-up of the SUMMIT study (Brittberg, 2018) a prospective randomized, open-label, parallel group, multicenter study. Five years after treatment, the improvement in MACI over microfracture in the co-primary endpoint of KOOS pain and function was maintained and was clinically and statistically significant (P = .022). Cartilage knee defects 3cm2 or larger treated with MACI were clinically and statistically significantly improved at 5 years compared with microfracture treatment.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
It is difficult to estimate the prevalence of cartilage lesions that would be eligible for ACI as it is difficult to determine exactly how many people in Australia may suffer from symptomatic cartilage lesions. It is estimated that between 5-11% of the general population have focal cartilage lesions (Bekkers 2012). Studies of prevalence of articular defects analyse the results of arthroscopic investigations. Widuchowski (2007) in a study of over 25,000 arthroscopies, noted that 7% of those patients under 40 and 9% of those under 50 were candidates for cartilage repair. The condition may be seen in conjunction with other common derangements of the knee including, ligamentous damage and mal-alignment of the patella-femoral joint. It is perhaps more useful to estimate prevalence by looking at the number of comparator procedures performed in Australia. The techniques currently available on the MBS for the repair of articular cartilage include microfracture. Evaluation of the number of cartilage repair procedures performed in the knee within Australia provides an estimate of the burden of repair of chondral defects on the health system. MBS statistics show that for

MBS item number 49576 KNEE (microfracture) - 1,581 procedures were recorded from July 2022 to June 2023.

It is intended that ACI be limited to patients aged between 18 and 55. An examination of Medicare Item Patient Demographic Reports reveals that 67% of all patients receiving microfracture are in this age range, therefore an estimate of the minimum eligible population in 2023 is 1059.

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

Year 1 estimated uptake (%):
13%

Year 2 estimated uptake (%):
18%

Year 3 estimated uptake (%):
23%

Year 3 estimated uptake (%):
28%

Estimate the number of patients who will utilise the proposed technology for the first full year:
80

Optionally, provide details:
There are approximately 40 ACI procedures currently performed annually in Australia. Most of these are knee patients. The patient must pay for the cost of the implant which is $6850. Should the procedure be included on the MBS and the implant subsequently included on the Prostheses List, it will become more accessible for patients with private health insurance. The cost of the implant will likely be a barrier to public patients accessing the procedure. As noted above, it is not anticipated that all comparator services will be replaced by the new procedure. It will also be dependent upon the patient's willingness to undergo both the harvesting and the implanting procedures and the willingness of hospitals to handle the biopsy and the implant. Noting these restraints, it is anticipated that demand for ACI will substantially increase if the financial barrier to access is removed and demand for the procedure is likely to double in the first year with a minimum of 80 procedures or approximately 8 percent of the eligible population in 2020.

It is estimated that the percentage of the eligible population that would receive ACI if it were included on the MBS and the implant included on the Prostheses List would increase by 5 percent annually and plateau at 40 percent of the eligible population over time. Assume 1.6% population growth with assumed eligible population of 1059 in 2023.

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 Knee Society Ltd
- Australian Orthopaedic Association

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

- Australian Knee Society Ltd
- Australian Orthopaedic Association

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

- Consumers Health Forum of Australia Ltd

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

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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

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?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
289402	Cellular Therapies - Chondrocytes - T - Ortho-ACI -Suspension - Vial

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

Codependent details

Please provide a rationale for the codependency:
The chondrocyte cells (Ortho-ACI™) are implanted during the medical services proposed by this application.

Are there any other sponsor(s) and / or manufacturer(s) that have similar prosthesis or device component in the Australian marketplace which this application is relevant to?
No

Are there any single and/or multi-use consumables delivered as part of the service or health technology?
Yes

Provide details:
The Ortho-ACI™ chondrocyte cells are seeded onto a collagen membrane prior to implantation. Currently Chondro Gide (ARTG 146887) is used however, any resorbable collagen membrane approved for use in cartilage repair can be used.

Fibrin glue is used to secure the cell-loaded membrane onto the cartilage defect.