

MSAC application 1629.1

**Defensive Antibacterial Coating
(DAC) with antibiotics for reducing
the risk of periprosthetic surgical site
infection**

Application or referral for other medical service or health technology

HPP Application number:

HPP200459

Application title:

Resubmission Defensive Antibacterial Coating (DAC) 5ml Kit plus antibiotic

Submitting organisation:

NOVAGENIT AUSTRALIA PTY LTD

Submitting organisation ABN:

33623078660

Application description

Succinct description of the medical condition/s:

Surgical Site Infections (SSI) are infections on the skin or soft tissue where the surgery took place. If left untreated, bacteria can travel deeper and infect the artificial implant, resulting in Periprosthetic Joint Infections (PJI) (Li 2022). This deeper, more serious condition often leads to implant failure and requires revision surgery.

Succinct description of the service or health technology:

Defensive Antibacterial Coating (DAC) 5 mL kit is a sterile, single-use Class III medical device designed to create a bioresorbable hydrogel coating on orthopaedic implants to reduce peri-implant infections caused by Gram-positive and Gram-negative aerobic and anaerobic bacteria during and after total joint arthroplasty (TJA).

DAC consists of two bioresorbable polymers: hyaluronic acid (HA) and polylactic acid. HA is a naturally occurring polysaccharide found within the extracellular matrix of connective tissue and has been shown to reduce bacterial adhesion and growth on coated surfaces (Zoccali 2021). Polylactic acid is a biodegradable synthetic polymer derived from renewable sources.

The product is supplied as a dry powder that is reconstituted with sterile water immediately before surgery and applied directly to the implant surface. Once applied, DAC forms a temporary physical barrier that inhibits bacterial adhesion and colonisation of the implant surface (Novagenit).

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:

NOVAGENIT AUSTRALIA PTY LTD

Application details

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

Prescribed List

Please provide justification for selecting the above program:

DAC is currently used within the public hospital system. This application seeks to expand that access to private hospital use and therefore requires listing on the Prescribed List (formerly known as the Prosthesis List). Defensive Antibacterial Coating 5mL Kit (DAC) is an implant and suitable for the prescribed list. DAC should be used in conjunction with an antibiotic, as per its TGA registration.

What is the type of service or health technology?

Therapeutic

PICO set

Application PICO set:

PICO set name
Defensive Antibacterial Coating (DAC) 5ml Kit plus antibiotic

Population

Describe the population in which the proposed health technology is intended to be used:

Population 1: Patients undergoing elective megaprosthesis or elective major revision for complete joint implants (for knee and hip) for indications other than periprosthetic infection including total joint revision, tumour removal and reconstruction. Applies only to a cementless or hybrid prosthesis.

Population 2: Patients undergoing surgery for periprosthetic infection for complete joint implants for knee and hip. Applies only to a cementless or hybrid prosthesis.

Select the most applicable Medical condition terminology (SNOMED CT):

Surgical site infection (disorder) SCTID: 433202001 433202001 |Surgical site infection (disorder)|

Intervention

Name of the proposed health technology:

Defensive Antibacterial Coating 5mL Kit (DAC) + antibiotic

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:

'No DAC' was previously accepted as the comparator by PASC.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Patients avoiding infections during prosthetic surgery experience a reduction in disease burden with less hospitalisation and risk of further revision surgery. Therefore, the use of DAC+antibiotic will change clinical practice for these patients.

Specified restrictions for funding

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

Proposed item:

AAAAA

Is the proposed item restricted?

Yes - restricted

Provide a short description of the restriction:

Population 1: Megaprosthesis or require revision surgery without infection.

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

For patients requiring megaprosthesis or revision surgery with no infection.

Proposed price of supply:

REDACTED

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

REDACTED

Provide details and explain:

REDACTED plus the cost of the antibiotic

Proposed item:

BBBBB

Is the proposed item restricted?

Yes - restricted

Provide a short description of the restriction:

Population 2: Patients require revision surgery and have an infection.

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

For patients requiring revision surgery with infection.

Proposed price of supply:

REDACTED

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

REDACTED

Provide details and explain:

REDACTED plus the cost of the antibiotic

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Currently in private hospitals there is no funding and patients have to pay for DAC. Public hospital use is funded via normal funding mechanisms.

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 clinical evidence provides evidence that DAC + antibiotic is superior to no DAC used during prosthetic surgery in the two populations.

Estimated utilisation

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

Based on the 2024 Australian registry data for infections in total knee and hip replacements, making allowance for a portion of 1st and 2nd revisions, limited to complete or total and cementless or hybrid revisions, in private hospitals only and including megaprotheses, for which there is data only for Distal Femoral, suggests 3,511 procedures (for 2024).

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 will use DAC+antibiotic in the first year and this represents REDACTED patients.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Once but some patients may need further revisions.

Optionally, provide details:

It is possible that it may be used more than once in those patients who require additional further revisions, or in the case of the megaprosthesis a first revision. The rate of infection is higher in 2nd revisions. At this stage it is not known whether surgeons would use DAC again in a second revision. This will need to be determined for the ADAR.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Once per revision.

Consultation

List all entities that are relevant to the proposed service / health technology.

Entities who provide the health technology/service:

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

AUSTRALIAN SOCIETY OF ORTHOPAEDIC SURGEONS

Entity impacted by the health technology/service:

AUSTRALIAN ORTHOPAEDIC ASSOCIATION

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

MUSCULOSKELETAL AUSTRALIA LTD.

AUSTRALIA AND NEW ZEALAND SARCOMA ASSOCIATION LIMITED

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?

Class III

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
427290	kit DAC - Implantable-device infection control barrier

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

Yes