Australian Government

Department of Health

Application Form

Defensive Antibacterial Coating (DAC) 5ml Kit

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 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): REDACTED
Corporation name: Novagenit Australia Pty Ltd
ABN: REDACTED
Business trading name: Novagenit Australia Pty Ltd

Primary contact name: REDACTED

Primary contact numbers
Business:
Mobile: REDACTED
Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers
Business:
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

DAC 5ml Kit (N001699)

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)

Patients at increased risk of peri-prosthetic infection due to colonisation of an orthopaedic implant during the implant procedure.
Condition 1: Patients with comorbidities known to increase the risk of infection receiving a primary joint implant.
Condition 2: Patients undergoing mega prothesis implantation or major revision joint implants for indications other than peri-prosthetic infection i.e. total joint revision, tumour removal and reconstruction.
Condition 3: Patients undergoing surgery for peri-prosthetic infection with implant replacement.
Condition 4: Patients undergoing open reduction and internal fixation.

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)

A new device for use in already established medical services is proposed. DAC is a kit designed for the preparation of a bio-resorbable hydrogel, composed of hyaluronan and poly-D,L-lactide copolymer, and its application to the surfaces of implants in the orthopaedic and traumatology fields. The function of DAC is to create a temporary physical barrier on the surface of an implanted device, thereby preventing the adhesion of planktonic bacteria and colonization of the surface, resulting in formation of biofilm; entirely at the discretion of the operating clinician. DAC powder may also be reconstituted with an aqueous solution of an appropriate antibiotic, which diffuses from the hydrogel to maintain a local concentration above the minimum inhibitory level for up to 72 hours. In order not to interfere with osteointegration, the bio-resorbable protective barrier generated by DAC hydrogel has been specifically designed to last for about 72 hrs, before being completely hydrolyzed.

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

☐ Yes
☒ No

(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? N/A

☐ Amendment to existing MBS item(s)
☐ New MBS item(s)

(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:

N/A

(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):

N/A

(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: N/A

☐ 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)*: N/A

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? N/A

☐ Yes
☐ No

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

Insert PBS item code(s) here

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

☐ 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?

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

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

Billing code(s): Insert billing code(s) here
Trade name of prostheses: Insert trade name here
Clinical name of prostheses: Insert clinical name here
Other device components delivered as part of the service: Insert description of device components here

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

☒ 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

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Insert sponsor and/or manufacturer name(s) here

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

Single use consumables: Sterile Water for Injection.
Multi-use consumables:

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: Hydrogel (hyaluronan and poly-D,L-lactide copolymer) implant.
Manufacturer's name: Novagenit
Sponsor's name: Novagenit Australia Pty Ltd

(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:
TGA approved indication(s), if applicable:
TGA approved purpose(s), if applicable:

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: 31/10/2019
Estimated date by which TGA approval can be expected: July 2020
TGA Application ID: DV-2019-CA-17985-1
TGA approved indication(s), if applicable:
TGA approved purpose(s), if applicable: The product is especially indicated in orthopaedic and traumatology as a preventive measure against bacterial adhesion, colonization and biofilm formation (which is cause of bacterial infections) on implant surface in the very early time window after implantation.

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? N/A

☐ Yes (please provide details below)
☐ No

Estimated date of submission to TGA:
Proposed indication(s), if applicable:
Proposed purpose(s), if applicable:

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.	Prospective, multicentre, randomised control trial	Romano, C.L., et al., Does an antibiotic-loaded hydrogel coating reduce early post-surgical infection after joint arthroplasty? J Bone Jt Infect, 2016. 1: 34-41	380 patients undergoing Primary or revision surgery randomised to DAC or No DAC – Primary outcome was surgical site infection rate and adverse events related to DAC. Prospective, multicentre, randomised control trial. Treated group: N=189; male 42.9%; mean age (SD)=69yr (12.6); McPherson host class B 65.6%, class C 10.6%; undergoing revision surgery for infection 28.2% (26.6% by 2-stage procedure). Control group: N=184; male 40.2%; mean age (SD)=71yr (10.6); McPherson host class B 69.0%, class C 7.6%; undergoing revision surgery for infection 28.3% (26.1% by 2-stage procedure). Follow-up =14.5 +/- 5.5mths	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5423565/	19 July 2016
2.	Prospective, multicentre, randomised control trial	Malizos, K., et al., Fast-resorbable antibiotic-loaded hydrogel coating to reduce post-surgical infection after internal osteosynthesis: a multicenter randomized controlled trial. J Orthop Traumatol, 2017. 18(2): 159-169	Randomised 256 patients over 18yr with a fresh (7 days) closed fracture requiring surgical reduction and internal fixation with either a metal plate and/or screws, or with an intramedullary nail to DAC or No DAC Treated group: N=126; male 42.1%; mean age (SD)=62.5yr (12.6); McPherson host class B 48.4%, class C 4.0%; major fracture sites=femur 37.3%, ankle/foot 25.4%, forearm/wrist 11.1%. Control group: N=127; male 44.9%; mean age (SD)=58.6yr (17.6); McPherson host class B 41.7%, class C 3.1%; major fracture sites=femur 25.2%, ankle/foot 22.8%, forearm/wrist 22.8%. Follow-up =18.1+/- 4.5mths	https://www.ncbi.nlm.nih.gov/pubmed/28155060	02 February 2017

	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***
3.	Case-control study.	Capuano, N., et al., One-stage exchange with anti-bacterial hydrogel coated implants provides similar results to two-stage revision, without the coating, for the treatment of peri-prosthetic infection. Knee Surg Sports Traumatol Arthrosc, 2018. 26(11): 3362-3367	22 cases undergoing 1-stage exchange hip or knee procedures, using cementless (hip) or partially cemented (knee) implants coated with DAC, matched for age, sex, infection site and host type with 22 controls undergoing 2-stage exchange hip or knee procedures, using cementless (hip) or partially cemented (knee) implants without DAC. Cases: 9 male, 13 female; mean age 71.3 ± 13.6yr; McPherson host class B+C 86.4%; revision for septic hip 22.7%, for septic knee 77.3%; 1st-stage MRSA population 52.1%. Controls: 9 male, 13 female; mean age 71.9 ± 8.3yr; McPherson host class B+C 81.8%; revision for septic hip 22.7%, for septic knee 77.3%; 1st-stage MRSA population 30.4%. Follow-up: 29.3± 5.0mth	https://www.ncbi.nlm.nih.gov/pubmed/29549387	26 November 2018
4.	Case-control study.	Zagra, L., et al., Two-stage cementless hip revision for peri-prosthetic infection with an antibacterial hydrogel coating: results of a comparative series. Int Orthop, 2019. 43(1): 111-115	27 cases undergoing 2-stage exchange hip procedure using cementless implants coated with DAC matched for age and host type with 27 controls without DAC operated on in the same time period. Inclusion criteria: delayed or late peri-prosthetic hip infection. Exclusion criteria: large soft-tissue defects; pervious failed revision for infection. Cases: 11male, 16 female; mean age 63.9 ± 11.7yr; McPherson host class B 70.4%, class C 25.9%; 1st-stage explant MRSA population 18.5%. Controls: 14 male, 13 female; mean age 64.8 ± 10.1yr; McPherson host class B 81.5%, class C 14.8%; 1st-stage explant MRSA population 18.5%. Follow-up: 2.7± 0.6yr	https://www.ncbi.nlm.nih.gov/pubmed/30374639	30 October 2018

	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***
5.	Consecutive Case Series	Zoccali, C, et al., Antibacterial Hydrogel Coating in the Prevention of Peri-prosthetic Joint Infection After Bone Reconstruction with Megaprothesis: a Consecutive Case Series	Forty-seven consecutive patients in three Centres received a megaprosthetic implant coated with Antibacterial-Loaded Hyaluronan Based Gel following tumour resection and limb salvage surgical procedure. Sites were Distal Femur (n=17) and Proximal Femur (n=19).	https://emsos.org/images/2019_EMSOS/EMSOS19._Abstract_Book.pdf	15 May 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, 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.***

Nil

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):**

    N/A

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

    N/A

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

    N/A

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

    N/A

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), INTERVENTION, 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:
That peri-prosthetic deep surgical site infection is a serious, devastating, condition, and one of the major causes of morbidity and surgical revision in joint arthroplasty, is well established [1]. The 5 year mortality and morbidity of a per-prosthetic joint infection has been characterised as worse than many cancers. In Australia as elsewhere, the seriousness of the condition is predicated on two sets of factors: clinical factors – the high risks of morbidity and mortality, and economic factors – the very substantial costs to the healthcare system [2].

The mortality risk of peri-prosthetic SSI is substantial. A 2018 systematic review of the literature found that patients undergoing total knee replacement had an SSI-related post-operative mortality rate of 4.33% in the first year, rising to 21.64% at 5 years, and, after adjusting for age, the odds of patients dying in the first year was 3.05 [3].

Patients who survive SSI are often debilitated by continued infection-related morbidity, which severely impacts their quality of life. A 2008 study from the Canberra Hospital showed that SSI patients were not only dissatisfied with the outcome of their surgery (as might be expected) but also experienced diminished quality of life, in terms of pain, stiffness, the ability to live independently and their mental health, amongst other dimensions [4].

The clinical and quality of life consequences of SSI are especially pronounced in already compromised patients, such as those with a tumour requiring major revision arthroplasty and a megaprosthesis, for whom the outcome of infection is commonly a high reinfection rate, perhaps leading to the loss of the limb and even death [5].Because of the serious clinical and disease burden, the cost implications of remediation of peri-prosthetic SSI is clearly also a serious issue. It is estimated that hospital costs for treatment of SSI in Australia are conservatively placed at $100,000 a case [2], and if initial treatment is unsuccessful, the additional expenditure associated with further surgical procedures and/or lengthy ongoing medical treatment runs to multiples of the cost of initial treatment [6]. With the rates of arthroplasty in Australia rising in step with an ageing population [7], it is clear that the number of SSI cases is also very likely to increase, and with that the economic burden on both the healthcare system and individual patients.

1. Kapadia BH, et al. Lancet 2016;387:386-94.
2. Choong PFM. ANZ J Surg 2011;81:1.
3. Lum ZC, et al. J Arthroplasty 2018;33:3783-3788.
4. Cahill JI, et al. J Orthopaed Surg 2008;16:58-65.
5. Sigmund IK, et al. PLoS ONE 2018;13:e0200304.
6. Peel TN, et al. J Hosp Infect 2013;85:213-219.
7. Australian Orthopaedic Association. National Joint Replacement Registry, Annual Report 2019.

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:**

    Risk factors for Peri-prosthetic Joint Infection include:

    Obesity, Diabetes Mellitus, use of disease modifying antirheumatic drugs, rheumatoid arthritis, immunosuppressed state, malignancy, American Society of Anesthesiology score >= 3 (Systemic Disease), colonisation with Staphylococcus aureus, previous arthroplasty or other surgery of the same joint, history of prior prosthetic joint infection, arthroplasty for management of fracture, prolonged procedure duration, and contaminated or dirty surgical site.

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):**

    Currently, prophylaxis against joint infection is provided by the use of systemic antibiotics.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

    DAC powder is reconstituted into a hydrogel at the time of surgery and applied immediately to the surface of the implanted device.

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

    Insert description of registered trademark component here

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?**

    Insert description of approach here

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):**

    If applicable, insert description of limitations here

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:**

    If applicable, insert description of resources or other medical services here

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

    DAC hydrogel would be applied to the surface of the implanted device by the operating surgeon at the time of surgery.

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

    Insert key components and clinical steps here

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

    If applicable, insert specification of limitations here

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:**

    If applicable, insert advice regarding training or qualifications

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

X Inpatient private hospital (admitted patient)
X Inpatient public hospital (admitted patient)
☐ Private outpatient clinic
☐ Public outpatient clinic
☐ Emergency Department
☐ Private consulting rooms - GP
☐ Private consulting rooms – specialist
☐ Private consulting rooms – other health practitioner (nurse or allied health)
☐ Private day surgery clinic (admitted patient)
☐ Private day surgery clinic (non-admitted patient)
☐ Public day surgery clinic (admitted patient)
☐ Public day surgery clinic (non-admitted patient)
☐ 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:

Describe rationale here

37. Is the proposed medical service intended to be entirely rendered in Australia?

X 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):

There is no other product like DAC in Australia. Therefore, the comparator is surgery with no DAC.

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

X Yes (please list all relevant MBS item numbers below)
☐ No

49318, 49319, 49324, 49327, 49330, 49333, 49336, 49346, 49509, 49512, 49517, 49518, 49527, 49530, 49533, 50215, 50218, 50224, 50227.

40. Define and summarise the current clinical management pathway/s 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):

Deep surgical site infection, if considered an acute infection, can be treated by a debridement and systemic antibiotics with implant retention of fixed components and replacement of exchangeable components (DAIR). DAIR patients receive post-operative antibiotics systemically for a number of days. Unsuccessful DAIR patients or chronic infections are treated with either a one-stage revision or two-stage revision. A one-stage revision requires the removal of all components, further debridement, pulse lavage and antibacterial washes with systemic antibiotic loading before implantation of new implantable devices. The new devices are often required to deal with bone loss due to the removal of the infected devices or to the infection process. Failure of a one-stage revision can lead to a further one-stage revision or a two-stage revision, or amputation. A two-stage revision requires the removal of all components followed by debridement and removal of all infected tissue, washouts utilising antibacterial agents and followed be reimplantation of an antibiotic-loaded cement spacer device. The patient undergoes a minimum of 6 weeks of systemic antibiotics until infection markers are acceptable to re-enter the joint and implant a new medical device. A two-stage procedure that fails may be followed by further surgical procedures, including amputation.

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

☒ In addition to (i.e. it is an add-on service)
☐ Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

Outline service/comparator substitution here

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 use of DAC will abolish, or at very least reduce, the need for current management procedures and resources required to manage surgical site infection.

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):

DAC has been shown to reduce deep surgical site infection associated with the implantation of an orthopaedic device when compared to the same procedures without DAC (see Section 17).

Please advise if the overall clinical claim is for:

☐ Superiority
☐ Non-inferiority

44. 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:

The safety outcomes with DAC are those which result from the abolition of, or reduction in, the risk of surgical site infection and the sequelae associated with the post-infection management procedures necessary.

Clinical Effectiveness Outcomes:

The major clinical outcome with DAC is the reduction in risk of surgical site infection (see Section 17).

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Insert prevalence and/or incidence here

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

As DAC would be applied at the time of surgery, it is unlikely that an average patient would receive it more than once.

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

Insert number of years here

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

Less than 100 patients.

49. 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:

Anticipated utilisation of DAC is under 500 patients over the first three years. The risk of 'leakage' is close to zero, because overall SSI is a relatively rare adverse outcome, about 2%, and surgeons would reserve DAC exclusively for situations where the risk of infection is high.

PART 8 – COST INFORMATION

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

The price of DAC 5ml is $2200.

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

Specify duration here

DAC is reconstituted and applied in a few minutes.

52. 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.

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