Australian Government

Department of Health

Application Form

(New and Amended Requests for Public Funding)

(Version 2.5)

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.

The application form will be disseminated to professional bodies / organisations and consumer organisations that have will be identified in Part 5, and any additional groups that the Department deem should be consulted with. The application form, with relevant material can be redacted if requested by the Applicant.

Should you require any further assistance, departmental staff are available through the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Phone: +61 2 6289 7550
Fax: +61 2 6289 5540
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): NA
Corporation name: Australian Breast Device Registry
ABN: NA
Business trading name: Australian Breast Device Registry

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 consultant acting on behalf of an Applicant?

☐ Yes
☒ No

(b) If yes, what is the Applicant(s) name that you are acting on behalf of?

Insert relevant Applicant(s) name here.

3. (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

4. Application title

Breast Magnetic Resonance Imaging for Breast Implant Associated Anaplastic Large Cell Lymphoma

5. 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)

Breast Implant Associated Anaplastic Large Cell Lymphoma is a rare T-cell derived lymphoma in the Non-Hodgkins Lymphoma family. It arises in the tissue around a breast implant, presenting with unilateral swelling, pain or enlargement of an implanted breast on average 7-10 years after initial implant placement. It presents in two ways; the seroma type, or in situ disease, consisting of a malignant effusion with or without the inner lining of the capsule involved. This form appears to have an indolent course, with cure obtained by removal of the implant and capsule involved. The mass type, or infiltrative disease, is less common but has a worse prognosis and is usually treated with surgery. It is unclear whether both are on the spectrum of lymphoproliferative disorders or separate diseases.

6. 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 use of MRI in women with breast implant associated anaplastic large cell lymphoma as demonstrated by seroma fluid which is positive for CD30 positive and ALK negative to stage disease. MRI would alter management.

7. (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?

☒ 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:

63464, 63467

(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

8. 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

9. 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
vi. ☐ Is for genetic testing for heritable mutations in clinically affected individuals and, when also appropriate, in family members of those individuals who test positive for one or more relevant mutations (and thus for which the Clinical Utility Card proforma might apply)

10. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☐ Prosthesis or device
☒ No

11. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

☐ 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

NA

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

Trade name: NA
Generic name: NA

12. (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): NA
Trade name of prostheses: NA
Clinical name of prostheses: NA
Other device components delivered as part of the service: NA

(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):

NA

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

Single use consumables: As per current item number MBS 63464
Multi-use consumables: As per current item number MBS 63464

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

14. (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: MRI machine
Manufacturer's name: Siemens, General Electric, Phillips
Sponsor's name: Various

(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

15. (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: Registered on ARTG (Medical Device Classification 4)
TGA approved indication(s), if applicable: Medical Device – Whole body MRI
TGA approved purpose(s), if applicable: Body imaging

16. 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

17. 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

18. **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.	Case control	Anaplastic large-cell lymphoma in women with breast implants JAMA 2008: 300(17): 2030-2035	Case control study using Dutch registry was the first to show an OR of 18.2 for women with breast implants and ALCL suggesting an association	Anaplastic large-cell lymphoma in women with breast implants	5.11.2008
2.	Case series – clinicopathological	Anaplastic large cell lymphoma involving the breast: a clinicopathologic study of 6 cases and review of the literature Arch Pathol Lab Med 2009:133(9):1383-1390	Case series with detailed pathological analysis	Anaplastic large cell lymphoma involving the breast: a clinicopathologic study of 6 cases and review of the literature	Sept 2009
3.	Meta analysis	Anaplastic large T-cell lymphoma and breast implants: a review of the literature Plast Recon Surg 2011: 128(3):651-661	Review of all reported cases with gross calculation of risk based on implants sold	Anaplastic large T-cell lymphoma and breast implants: a review of the literature	Sept 2011

	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***
4.	Meta analysis/systematic review	Anaplastic large cell lymphoma and breast implants: a systematic review Plast Recon Surg 2011:127(6):2141-2150	Systematic review	Anaplastic large cell lymphoma and breast implants: a systematic review	June 2011
5.	Rand Corporation Expert Consensus	Anaplastic large cell lymphoma and breast implants: results from a structured expert consultation process Plast Recon Surg 2011:128(3):629-639	Expert consensus on BIA-ALCL	Anaplastic large cell lymphoma and breast implants: results from a structured expert consultation process	Sept 2011
6.	Case control	ALK-1-negative anaplastic large cell lymphoma associated with breast implants: a new clinical entity Clin Breast Cancer 2011: 11(5):283-296	Case control report between NHL of breast and ALCL to show it is a distinct clinicopathological entity	ALK-1-negative anaplastic large cell lymphoma associated with breast implants: a new clinical entity	October 2011

	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***
7.	Experimental	Breast implant-associated, ALK-negative, T-cell, anaplastic, large-cell lymphoma: establishment and characterization of a model cell line (TLBR-1) for this newly emerging clinical entity Cancer 2011:117(7):1478-1489	Establishment of tumour cell line	Breast implant-associated, ALK-negative, T-cell, anaplastic, large-cell lymphoma: establishment and characterization of a model cell line (TLBR-1) for this newly emerging clinical entity	1.4.2007
8.	Case series	Primary anaplastic large-cell lymphoma associated with breast implants Leuk Lymphoma 2011:51(8):1481-1487	Case series of patients with ALCL	Primary anaplastic large-cell lymphoma associated with breast implants	August 2011
9	Case series	Anaplastic large cell lymphoma associated with breast implants: a report of 13 cases Am J Surg Pathol 2012:36(7):1000-1008	Large case series with clinicopathological analysis	Anaplastic large cell lymphoma associated with breast implants: a report of 13 cases	July 2012

	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***
10.	Meta analysis	Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis Curr Hematol Malig Rep 2013: 8(3) : 196-210	Meta analysis of reported cases showing worse prognosis for mass disease	Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis	Sept 2013
11.	Cohort study	Breast implants and anaplastic large-cell lymphoma: a danish population-based cohort study Cancer Epidmiol Biomarkers Prev 2013:22(11):2126-9	Cohort study showed no higher risk in women with breast implants	Breast implants and anaplastic large-cell lymphoma: a danish population-based cohort study	November 2013
12.	Case series	Breast implant-associated anaplastic large cell lymphoma: sensitivity, specificity, and findings of imaging studies in 44 patients Breast Cancer Res Treat 2014: 147(1):1-14	Clinical series focussing on radiological assessment and their sensitivity and specific	Breast implant-associated anaplastic large cell lymphoma: sensitivity, specificity, and findings of imaging studies in 44 patients	Aug 2014

	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***
13.	Case series	Breast implant-associated anaplastic large-cell lymphoma: long-term follow-up of 60 patients J Clin Oncol 2014:32(2):114-120	Long term follow up evaluating modalities of therapy and survival for 60 patients	Breast implant-associated anaplastic large-cell lymphoma: long-term follow-up of 60 patients	10.1.2014
14.	Case series	Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases Plast Recon Surg 2015:135(3):695-705	Largest case series reported	Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases	March 2015
15.	Systematic review	Breast implant-associated anaplastic large cell lymphoma: a systematic review Plast Recon Surg 2015:135(3):713-720	Systematic review of 54 caes	Breast implant-associated anaplastic large cell lymphoma: a systematic review	March 2015

	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***
16	Experimental	Bacterial Biofilm Infection Detected in Breast Implant-Associated Anaplastic Large-Cell Lymphoma Plast Recon Surg 2016:137(6):1659-1669	First study to detect bacteria in high numbers in BIA-ALCL suggesting bacterial aetiology	Bacterial Biofilm Infection Detected in Breast Implant-Associated Anaplastic Large-Cell Lymphoma	June 2016
17	Government notification TGA, Expert panel report	Breast implants - Expert advisory panel advice on association with anaplastic large cell lymphoma		Breast implants - Expert advisory panel advice on association with anaplastic large cell lymphoma	Jan 30 2017

** 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.*

19. 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.	Case series	**Breast implant associated Anaplastic Large Cell Lymphoma in Australia and New Zealand – high surface area textured implants are associated with increased risk** **Plast Recon Surg** **Under review**	Latest Australian and New Zealand patient series using implant sales to calculate implant specific risk. High surface area implant textures show highest risk for BIA ALCL	n/a	Submitted January 2017

** 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

20. 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):

Breast surgeons, plastic surgeons, cosmetic surgeons, radiologists.

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

Royal Australian and New Zealand College of Radiologists (RANZCR); Breast Surgeons (BreastSurgANZ); Australian Society of Plastic Surgeons; Australasian College of Cosmetic Surgeons.

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

There is no relevant consumer organisation. The disease is rare.

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

Various machine manufacturers.

24. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

REDACTED

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

25. 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:

Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is a rare T-cell derived lymphoma within the Non-Hodgkin lymphoma group. It arises in the effusion or in the scar capsule surrounding a breast implant. It presents with unilateral swelling, pain or enlargement of a breast with an implant.

The natural history is that BIA-ALCL presents in one of two ways. The seroma type, or *in situ* disease, consists of a malignant effusion with or without the inner lining of the capsule involved. This form has an indolent course, and cure is obtained by removing the implant and the capsule. The mass type, or infiltrative disease, has a poorer prognosis and requires surgery with adjuvant chemotherapy (cyclophosphamide, doxorubicin, vincristine, prednisolone). It is not clear at this time whether these are both on the spectrum of lymphoproliferative disorders, or whether they are separate diseases. BIA-ALCL is an emerging disease. The first case was reported in 1997, and in Australia in 2007. Since then 46 cases have been recorded, including three deaths. Australia appears to have a higher per capita incidence than other countries around the world. Improved recognition of this condition means that the number of diagnoses of BIA-ALCL increase.

The forty-six confirmed cases of BIA-ALCL in Australian women were identified between 2007 and 2016. They occurred 3 to 14 years after breast implants were inserted (range 1 to 37 years) and typically the median interval is about 10 years. The TGA updated its website on 20th December 2016 confirming that a causal link with breast implants is likely. All cases of BIA-ALCL occurred in women who had been exposed to implants with surface rendering that was either textured or polyurethane, with none recorded in women who had had implants with smooth surfaces.

26. 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:

For investigation of effusion, enlargement, pain or inflammation of a breast in the presence of a breast implant, an ultrasound of the breast and lymph node area should be ordered first. If US shows an effusion the patient should progress to fine needle aspirate. If US shows mass+/- lymph node involvement+/- effusion, the patient should progress to biopsy and oncology consult. In Australian guidelines all patients with confirmed ALCL have MRI for use in surgical planning and staging, and PET/CT for staging.

The service would be delivered by private radiology practices and public radiology departments within hospitals.

27. 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):

Clinical management plan before the patient uses the proposed medical services includes ultrasound scan and fine needle aspirate. Please see APPENDIX _ for the American Society of Plastic Surgeons Flow chart and Australian Guidelines.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Breast MRI would be used for patients when ALCL is diagnosed on seroma fluid analysis for use in surgical planning (defining tumour planes) and staging.

Breast MRI takes approximately one hour, and only one test is likely to be required.

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

    NA

30. **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?**

    NA

31. **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):**

    MRI of the breast can be undertaken in public or private hospitals, or private radiology clinics. As it stands the MBS funds breast MRI only for asymptomatic high risk women under the age of 50 or PIP implants. Patients who do not meet these criteria are required to self-fund their breast MRI. MRI would only be available if ALCL is diagnosed.

    Publicly funded MRI breast would be limited to one a year.

32. **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:**

    Nil

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

    Specialist surgeons, medical oncologists would provide a referral for breast MRI.

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

    NA

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

    Delivered by qualified radiologists and radiographers.

    Referral – Not directly from a GP.

36. **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:**

    Suitably qualified radiologists and radiographers.

37. **(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:

Breast MRI can be undertaken in private or public settings, allowing wide access to this service.

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

☒ Yes
☐ No – please specify below

Specify further details here

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

39. 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):

US is commonly used to image an enlarged implanted breast, and it is envisaged that this will continue to be the primary breast imaging modality, with MRI if ALCL is confirmed.

Comparators would be CT/PET scanning used as part of lymphoma workup. Mammography has no role.

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

☒ Yes
☐ No

MBS 61620

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):

Following histologic confirmation of BIA-ALCL, MRI is performed to determine extent of disease for planning oncologic surgery. A multi-disciplinary team including surgeon, oncologist, surgical oncologist and pathologist assess the extent of the disease, and a referral is made to an oncologist where a lymphoma workup and staging including PET/CT scanning is performed. If localised, total capsulectomy and explantation of both implants is recommended with monitoring by an oncologist. If advanced disease is found, explantation +/- lymph node clearance is undertaken with adjuvant chemotherapy decided by a multi-disciplinary meeting.

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

☒ Yes
☐ No

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

Breast MRI is expected to augment current MBS funded US of the breast in women with confirmed ALCL.

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):

They will not change, except for the addition of MRI.

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):

A) MRI is used for surgical planning and staging once BIA-ALCL is histologically proven. The MRI can confirm the extent of disease, and the MRI would alter the management, and lead to more accurate initial surgery.

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: MRI is superior to US in determining the size and location of the ALCL lesion in the breast.

MRI will allow more appropriate first line treatment i.e. whether capsulectomy should be performed, and whether chemotherapy will be required.

MRI may make initial surgery more likely to be just one procedure rather than the need for repeat surgery due to close tumour margins.

Clinical Effectiveness Outcomes: This should result in improved outcomes for the patient in terms of complications and cosmesis, and potentially lower recurrence rates.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Between 2007 and 2016 there have been 46 cases of BIA-ALCL diagnosed in Australia. The rate of diagnosis is expected to rise with better awareness, better testing capabilities, and greater uptake of textured breast implants in Australia, however it is expected to remain a rare condition.

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

Annual utilisation per patient is one scan in one year with no repeats envisaged in most circumstances.

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

MRI breast would be required only once, or if follow up indicated a new lesion which was not well characterised on conventional imaging.

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

We would expect, based on recent diagnosis rates, that the number of cases of ALCL to be diagnosed annually in Australia would be approximately 10 per year. The proposed medical service would be restricted to women in proven BIA-ALCL.

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:

The uptake of the proposed medical service is likely to be low, given the number of cases of BIA-ALCL. Leakage is unlikely.

PART 8 – COST INFORMATION

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

MRI of the breast - 63487

MRI-performed under the professional supervision of an eligible provider at an eligible location, if:

(a) the patient is referred by a specialist or a consultant physician; and

(b) a dedicated breast coil is used; and

(c) the request for the scan identifies that:

(i) the patient has been diagnosed with metastatic cancer restricted to the regional lymph nodes; and (ii) clinical examination and conventional imaging have failed to identify the primary cancer

Fee: $690.00 Benefit: 75% = $517.50 85% = $609.80

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

1 hour

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.

Category: Category 5 – Diagnostic imaging services
Proposed item descriptor: MBS [item number] MAGNETIC RESONANCE IMAGING performed under the professional supervision of an eligible provider at an eligible location where the patient is referred by a specialist or by a consultant physician and where: (a) a dedicated breast coil is used; and (b) the request for scan identifies that the patient has a breast implant in situ, and ALCL has been diagnosed. Fee: $ As per current fee ($690) for screening MRI in high risk women

PART 9 – FEEDBACK

The Department is interested in your feedback.

54. How long did it take to complete the Application Form?

10 hours

55. (a) Was the Application Form clear and easy to complete?

☒ Yes
☐ No

(b) If no, provide areas of concern:

What comparators means.

56. (a) Are the associated Guidelines to the Application Form useful?

☒ Yes
☐ No

(b) If no, what areas did you find not to be useful?

Insert feedback here

57. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

☐ Yes
☒ No

(b) If yes, please advise:

Insert feedback here