



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

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Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

REDACTED

Primary contact name: REDACTED

REDACTED

Alternative contact name: REDACTED

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

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)

The use of MRI in women newly diagnosed with cancer to offer local staging when conventional imaging with mammography and US is likely to understage the disease. This includes women with a significant discrepancy between clinical examination findings and conventional imaging findings where the confirmation of more extensive disease on MRI would alter management.

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 newly diagnosed with breast cancer

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

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

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): 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

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

If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

- Yes (please provide details below)
 No

Date of submission to TGA: Insert date of submission here

Estimated date by which TGA approval can be expected: Insert estimated date here

TGA Application ID: Insert TGA Application ID here

TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

- 16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

- Yes (please provide details below)
 No

Estimated date of submission to TGA: Insert date of submission here

Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)

Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
	For each key journal article or published research relating to your proposed service, insert the type of study design in this column and columns below	For each key journal article or published research relating to your proposed service, insert the title of article or research (including any trial identifier or study lead if relevant) in this column and columns below	For each key journal article or published research relating to your proposed service, insert a short description of research in this column and columns below	For each key journal article or published research relating to your proposed service, insert a website link to journal article or research (if available) in this column and columns below	For each key journal article or published research relating to your proposed service, insert the date of publication in this column and columns below

	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, randomized Multi center study (440 breast cancer patients < 56 years)	Gonzalez et al. (2014), Preoperative MRI of the Breast (POMB) Influences Primary Treatment in Breast Cancer: A Prospective, Randomized, Multicenter Study	The purpose of this study was to determine whether preoperative breast MRI would affect primary surgical management, reduce reexcision/reoperation procedures, and influence the choice of neoadjuvant treatment in patients with newly diagnosed breast cancer.	https://www.ncbi.nlm.nih.gov/pubmed/24817517	July 2014
2.	Meta-analysis	Houssami et al. (2013), Preoperative magnetic resonance imaging in breast cancer: meta-analysis of surgical outcomes.	Investigating the effect of preoperative MRI compared with standard preoperative assessment on surgical outcomes, focusing on studies that used a controlled design.	https://www.ncbi.nlm.nih.gov/pubmed/23187751	Feb 2013

	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.	A decision analytic model	Young et al. (2012) Preoperative breast MRI in early-stage breast cancer	A decision analytic model was developed to evaluate the impact of adding breast MRI to the preoperative evaluation of women with early-stage breast cancer who were candidates for breast-conserving therapy on patient outcomes measured in quality-adjusted life years (QALYs).	http://dx.doi.org/10.1007/s10549-012-2207-1	Oct 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***
4.	Open, parallel group trial in 45 UK centres, with 1623 women aged 18 years or older with biopsy-proven primary breast cancer who were scheduled for wide local excision after triple assessment.	Turnbull et al. (2010) Comparative effectiveness of MRI in breast cancer (COMICE) trial: a randomised controlled trial	This study assessed the clinical efficacy of contrast-enhanced MRI in women with primary breast cancer.	http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)62070-5/abstract	Feb 2010
5.	Systematic Review	Marinovich et al.2012 Early prediction of pathologic response to neoadjuvant therapy in breast cancer: systematic review of the accuracy of MRI.	This systematic literature search examines the evidence for MRI's accuracy in early response prediction during neoadjuvant chemotherapy in breast cancer.	https://www.ncbi.nlm.nih.gov/pubmed/22863284	Oct 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***
6.	Retrospective review	Pengel et al 2014 Avoiding preoperative breast MRI when conventional imaging is sufficient to stage patients eligible for breast conserving therapy	To determine when preoperative breast MRI will not be more informative than available breast imaging and can be omitted in patients eligible for breast conserving therapy	http://dx.doi.org/10.1016/j.ejrad.2013.10.018	Feb 2014
7.	A single-center, prospective, nonrandomized comparison study	Riedl et al 2015. Triple-modality screening trial for familial breast cancer underlines the importance of magnetic resonance imaging and questions the role of mammography and ultrasound regardless of patient mutation status, age, and breast density.	To evaluate the breast cancer screening efficacy of mammography, ultrasound, and magnetic resonance imaging (MRI) in a high-risk population and in various population subgroups.	https://www.ncbi.nlm.nih.gov/pubmed/25713430	April 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***
8.	Retrospective Review	Harvey et al 2016 An Abbreviated Protocol for High-Risk Screening Breast MRI Saves Time and Resources	To review the ability of an abbreviated, high-risk, screening, breast MRI protocol to detect cancer and save resources.	https://www.ncbi.nlm.nih.gov/pubmed/27814819	Nov 2016
9.	Systematic Review	Housammi et al 2008 Accuracy and Surgical Impact of Magnetic Resonance Imaging in Breast Cancer Staging: Systematic Review and Meta-Analysis in Detection of Multifocal and Multicentric Cancer	Systematic review and meta-analysis of the accuracy of MRI in detection of multifocal (MF) and/or multicentric (MC) cancer not identified on conventional imaging.	http://ascopubs.org/doi/pdf/10.1200/jco.2007.15.2108	July 2008

	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.		Sardanelli et al 2010 Magnetic resonance imaging of the breast: Recommendations from the EUSOMA working group	The use of breast magnetic resonance imaging (MRI) is rapidly increasing. EUSOMA organised a workshop in Milan on 20–21st October 2008 to evaluate the evidence currently available on clinical value and indications for breast MRI.	http://dx.doi.org/10.1016/j.ejca.2010.02.015	May 2010
11.	Review	Spick et al 2015 Breast MRI used as a problem-solving tool reliably excludes malignancy	To evaluate the diagnostic performance of breast MRI if used as a problem-solving tool in BI-RADS 0 cases.	http://dx.doi.org/10.1016/j.ejrad.2014.10.005	Jan 2015
12.	Prospective registry study	Bedrosian et al. A Cost Analysis of Preoperative Breast MRI Use for Patients with Invasive Lobular Cancer	This study aimed to evaluate whether MRI use for women with invasive lobular carcinoma (ILC) significantly changes the cost of care	https://www.ncbi.nlm.nih.gov/pubmed/26156655	Jan 2016

	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.	Review.	Mango et al. Abbreviated protocol for breast MRI: Are multiple sequences needed for cancer detection?	To evaluate the ability of an abbreviated breast magnetic resonance imaging (MRI) protocol, consisting of a precontrast T1 weighted (T1W) image and single early post-contrast T1W image, to detect breast carcinoma	http://dx.doi.org/10.1016/j.ejrad.2014.10.004	Jan 2015
14.	Retrospective review	Caramella et al Value of MRI in the surgical planning of invasive lobular breast carcinoma: a prospective and a retrospective study of 57 cases: Comparison with physical examination, conventional imaging, and histology	To determine the value of magnetic resonance imaging (MRI) for the surgical planning of invasive lobular carcinoma (ILC)—a diagnostic challenge for radiologists.	http://ac.els-cdn.com/S0899707107000022/1-s2.0-S0899707107000022-main.pdf?_tid=4e1bbf18-0d6c-11e4-82c7-00000aacb35d&acdnat=1405572134_80ed72b9ac6bc3193d638ff197c88585	May 2007

	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***
15.	Retrospective review	McGhan et al Use of preoperative magnetic resonance imaging for invasive lobular cancer: good, better, but maybe not the best?	Invasive lobular cancer (ILC) of the breast is difficult to diagnose clinically and radiologically. It is hoped that preoperative magnetic resonance imaging (MRI) can improve evaluation of extent of disease.	http://dx.doi.org/10.1245/s10434-010-1266-y	Oct 2010
16.	Retrospective review	Bernardi et al. 2012 EUSOMA criteria for performing pre-operative MRI staging in candidates for breast conserving surgery: Hype or helpful?	A validation study of EUSOMA criteria that recommend selection of breast conserving surgery (BCS) candidates to pre-operative MRI.	http://dx.doi.org/10.1016/j.breast.2012.05.007	June 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***
17.	Retrospective review	Mann et al 2010 The impact of preoperative breast MRI on the re-excision rate in invasive lobular carcinoma of the breast	Assessed the influence of preoperative breast MRI on the re-excision rate and the rate of mastectomies.	http://dx.doi.org/10.1007/s10549-009-0616-6	Jan 2010
18.	Retrospective review	Iacconi et al 2016 Multicentric Cancer Detected at Breast MR Imaging and Not at Mammography: Important or Not?	Review of the magnetic resonance (MR) imaging and pathologic features of multicentric cancer detected only at MR imaging and to evaluate its potential biologic value.	https://www.ncbi.nlm.nih.gov/pubmed/26605912	May 2016

	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***
19.	Retrospective to linked SEER-Medicare dataset	Fortune-Greely et al 2014 Preoperative breast MRI and surgical outcomes in elderly women with invasive ductal and lobular carcinoma: a population-based study	To determine if patients differentially benefit from breast MRI, surgical outcomes—initial mastectomy, reoperation, and final mastectomy rates—among patients grouped by histologic type were examined.	http://dx.doi.org/10.1007/s10549-013-2787-4	Jan 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***
20.	Retrospective review	Freitas et al 2013 Added cancer yield of breast magnetic resonance imaging screening in women with a prior history of chest radiation therapy.	Recommendation for breast magnetic resonance imaging (MRI) screening for women with a prior history of chest radiation is currently based on expert opinion, because existing data are very scant. The objective of this study was to evaluate added cancer yield of screening breast MRI in this population.	https://www.ncbi.nlm.nih.gov/pubmed/22952042	Feb 2013
21.	Prospective	Liu et al 2014 Multicenter prospective study of magnetic resonance imaging prior to breast-conserving surgery for breast cancer.	This multicenter prospective study aimed to assess the utility of dynamic enhanced magnetic resonance imaging (MRI) prior to breast-conserving surgery for breast cancer.	http://europepmc.org/abstract/med/24985573	2014 PMID:24985573

	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***
22.	Prospective	Nori et al 2014 Role of preoperative breast MRI in ductal carcinoma in situ for prediction of the presence and assessment of the extent of occult invasive component.	The aim of this study was to evaluate the role of preoperative magnetic resonance imaging (MRI) in determining occult invasive presence and disease extent in patients with preoperative diagnosis of pure DCIS.	https://www.ncbi.nlm.nih.gov/pubmed/24750509	May June 2014
23.	Review	Obdeijn et al 2013 Preoperative breast MRI can reduce the rate of tumor-positive resection margins and reoperations in patients undergoing breast-conserving surgery	Breast cancer patients eligible for breast-conserving surgery, were evaluated whether the information provided by preoperative MRI of the breast would result in fewer tumor-positive resection margins and fewer reoperations.	https://www.ncbi.nlm.nih.gov/pubmed/23345350	Feb 2013

* 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. Leave this blank

	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.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
6.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
7.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
8.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
9.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
10.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

	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***
11.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
12.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
13.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
14.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
15.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Radiologists, Breast Surgeons, Medical Oncologists, Radiation Oncologists

- 20. 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); Medical Oncology Group of Australia Incorporated (MOGA)

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

Breast Cancer Network Australia (BCNA) Supporting document attached (Appendix 1)

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

Various machine manufacturers as per attached ARTG Schedule attached (Appendix 2)

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

REDACTED

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

23. 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:

According to the Australian Institute of Health and Welfare's Breast Cancer in Australia: An overview 2009, breast cancer is the commonest cancer in women comprising 28% of all cancers reported in women in 2006. That year, 12,614 women were diagnosed with invasive breast cancer while 1,559 women were diagnosed with ductal carcinoma in situ, the pre-cursor to invasive breast cancer. Because of the aging population, breast cancer is expected to increase with an estimated 22% increase in number of patients with breast cancer by 2015, giving an approximate 15,400 patients to be diagnosed last year (AIHW, 2009).

Breast cancer is the second commonest cause of cancer-related deaths with 2,618 women dying from this disease in 2006 (AIHW, 2009).

At the end of 2006, 143,967 women had been diagnosed with breast cancer in the past 25 years, giving a 25-year prevalence of 1.4% of the female population (AIHW, 2009).

In 2003, breast cancer was the sixth leading cause of burden of disease for females (60,520 disability-adjusted life years [DALYs]), accounting for 5% of all female burden of disease and 26% of all female burden due to cancer, and on par with burden of disease caused by dementia and type 2 diabetes (AIHW, 2009).

Overall, breast cancer recurrences occur more frequently in the first 2 years, decreasing thereafter with an average rate of recurrence of 4.3% per year for years 5-12 post-treatment (Saphner T et al, Journal of Clinical Oncology 1996). Breast cancer can be very broadly divided into 2 groups which behave differently. Hormone receptor positive breast cancers, which comprises 70% of breast cancer, is commonly associated with late recurrences, typically in the bones, with an annual risk of distant recurrence following adjuvant anti-estrogen therapy of 1% to 4% (Lim E et al, Oncology 2012). Triple negative breast cancer, on the other hand, is an aggressive subtype which comprises about 15% of all breast cancers. Because the patients with this subtype of cancer tend to be younger and the tumours tend to grow more rapidly, mammographic detection of these tumours may be difficult. Patients with this breast cancer subtype tend to recur early, within the first 2 years, in the brain or lungs (Foulkes WD et al. NEJM 2010; 363: 1938-48).

24. 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:

- A) The use of MRI in women newly diagnosed with cancer to offer local staging when conventional imaging with mammography and US is likely to understage the disease. Specifically this includes women with a significant discrepancy between clinical examination findings and conventional imaging findings where the confirmation of more extensive disease on MRI would alter management. This is likely to occur more frequently in women diagnosed with breast cancer under 50 years, those with very dense breasts, and in some subtypes of breast cancer for eg. Invasive lobular cancer; and
- B) The use of MRI to characterise a lesion when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy has not been possible (e.g. possible distortion on only one mammographic view without a sonographic correlate).

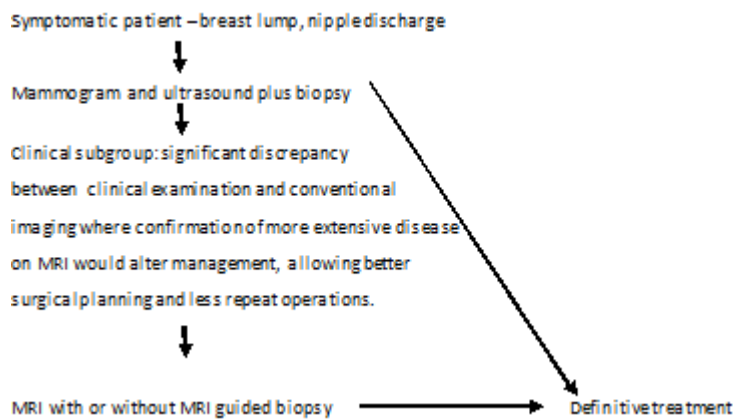
The proposed medical service would be delivered at private radiology practices and radiology departments in public hospitals.

25. 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):

Patients diagnosed with breast cancer present either with a palpable lump or abnormality noted on screening (usually on mammogram and confirmed on ultrasound). These patients undergo triple assessment – clinical examination, imaging (mammogram and ultrasound) and pathological assessment (fine needle aspiration biopsy or core biopsy).

There is no potential for inappropriate medicalisation of a previously untreated condition.

This is generally standard management of patients with suspected breast cancer.



PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Breast MRI would be used for patients where there is a discrepancy between clinical findings and conventional imaging and thus potential under-staging of disease, and where improved local staging would alter management of a breast cancer.

It would also be used in the rare situation where there is a need to characterise a suspicious lesion when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy has not been possible.

Breast MRI generally takes up to 1 hour, and only one test is likely to be required (unless a further MRI guided biopsy is required).

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

Not applicable

28. 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?

Not applicable

29. 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):

Breast MRI can be undertaken in public or private hospitals or private radiology practices. Currently, the MBS only funds breast MRI for asymptomatic high risk women under the age of 50. Breast MRI is not otherwise publicly funded in either the private or public setting and patients who do not meet the MBS criteria have to self-fund their breast MRI.

Publicly funded breast MRI would be limited to one a year unless a subsequent MR guided biopsy was needed.

30. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

Nil.

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

Radiologists with assistance from radiographers

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

Not applicable

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

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

34. 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

35. (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

(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 public or private hospitals or private radiology practices. Currently, the MBS only funds breast MRI for asymptomatic high risk women under the age of 50. Breast MRI is not otherwise publicly funded in either the private or public setting and patients who do not meet the MBS criteria have to self-fund their breast MRI.

36. 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)

- 37. 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):**

Both mammography and breast ultrasound are commonly used to image a breast cancer, and it is envisaged they will continue to be the prime breast imaging modalities with MI supplemental in highly selected cases

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

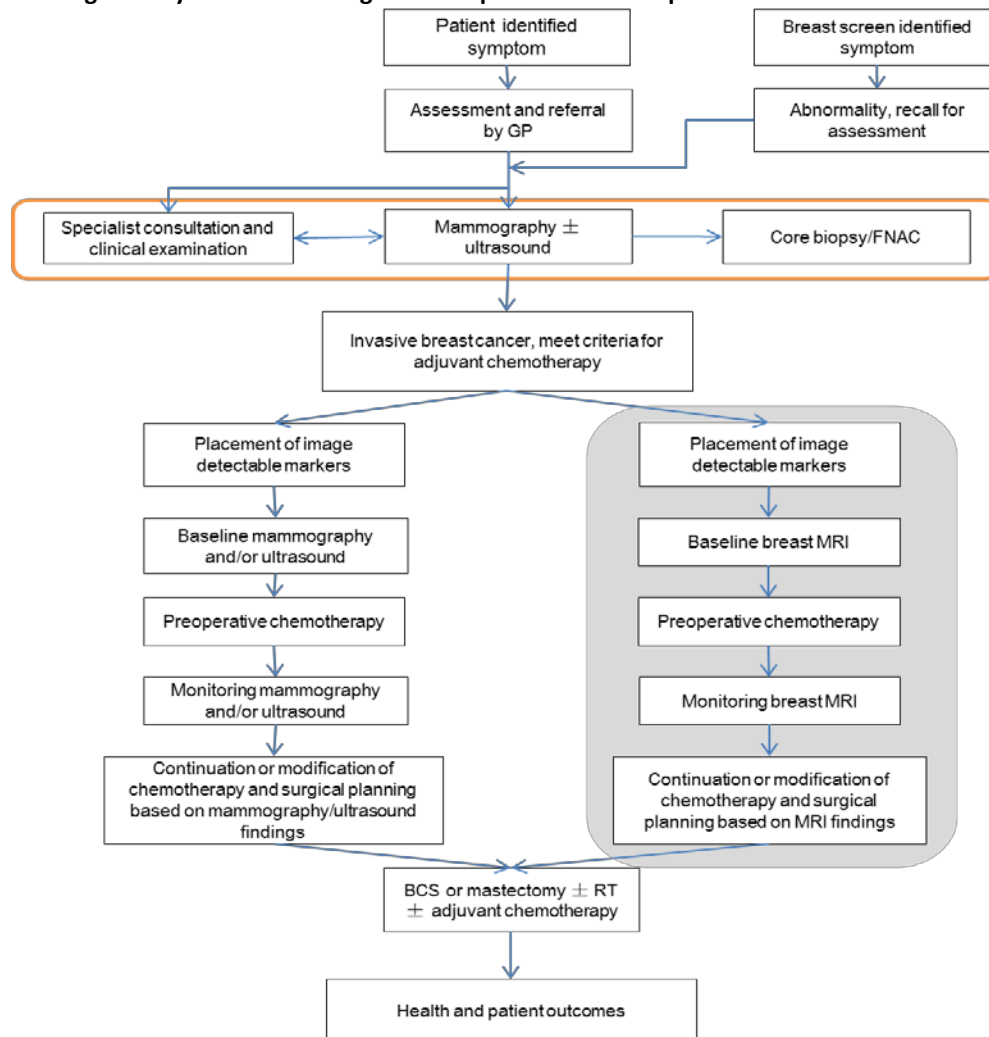
- Yes (please provide all relevant MBS item numbers below)
 No

MBS 63464, 63467

39. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

Patients diagnosed with breast cancer present either with a palpable lump or abnormality noted on screening (usually on mammogram and confirmed on ultrasound). These patients undergo triple assessment – clinical examination, imaging (mammogram and ultrasound) and pathological assessment (fine needle aspiration biopsy or core biopsy).

This is generally standard management of patients with suspected breast cancer.



40. (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 publicly funded imaging with mammography and ultrasound in a small number of women with diagnosed cancer as per the indications specified in this application.

41. 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 in selected cases and extremely rarely MRI guided biopsy.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

42. 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) The use of MRI in women diagnosed with cancer to offer local staging when conventional imaging with mammography and US is likely to understage the disease or not visualize the disease and where a significant discrepancy between clinical examination findings and conventional imaging findings is such that confirmation of more extensive disease on MRI would alter management. In these cases MRI will lead to more accurate initial surgery.

- B) The use of MRI to characterise a lesion when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy has not been possible (e.g. possible distortion on only one mammographic view without a sonographic correlate). In these cases MRI will lead to a more accurate diagnosis either malignant or benign and thus more appropriate initial management.

43. 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:

MRI is superior to mammogram and ultrasound in determining the size and location of the primary cancer in the breast

For selected cases MRI will allow more appropriate first line treatment ie neoadjuvant chemotherapy, definitive breast conserving treatment or mastectomy, uni or bilateral

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

This should result in cost savings of the patient and system, improved outcomes for the patient in terms of complications and cosmesis, and potential lower recurrence rates,

May add other benefits....

MRI and MRI or US guided biopsy may identify lesions and reduce the need for open diagnostic surgery.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

At the end of 2006, 143,967 women had been diagnosed with breast cancer in the past 25 years, giving a 25-year prevalence of 1.4% of the female population (AIHW, 2009)

46. 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), unless having MRI guided biopsy, where the patient would require 2 in one year.

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

A patient would have breast MRI not more frequently than once unless a subsequent MR guided biopsy was needed, or if follow up post breast cancer with MRI is indicated due to possible new lesion which is not characterised well on conventional imaging.

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

We propose to use MRI mainly in the incident cases of breast cancer rather than prevalent cases. There are about 15,000 new cases of breast cancer diagnosed in Australia each year, the vast majority of which are more than adequately worked up with conventional imaging. The proposed medical service would be restricted to women in whom there is a significant discrepancy between clinical examination findings and conventional imaging findings where the confirmation of more extensive disease on MRI would alter management, and in a very small group where other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy has not been possible but there is a very high index of suspicion.

We have undertaken two large audits at Royal Perth Hospital and Mater Hospital, North Sydney to better understand the current use of MRI in specialist units.

These confirm there is a small but significant number of women diagnosed with breast cancer in whom there is difficulty in estimating the lesion size from conventional assessment techniques, and in whom the experienced multidisciplinary breast team feel the addition of breast MRI will lead to better surgical planning with less uncertainty, less repeat operations and superior outcomes in terms of amount of surgery and poor cosmesis from repeat operations.

Data from the Mater since April 2010 to end 2015 when breast MRI for selected cases was available to assist in treatment planning have recently been presented at the 10th General Breast Imaging Meeting of RANZCR in July 2015. This shows MRI was performed in 12.5% of newly diagnosed cases (excluding for neo-adjuvant chemotherapy planning or occult primary). Further details are supplied in an Appendix 3 attached.

Data from Royal Perth Hospital (unpublished with details in Appendix 4) show that MRI in this public hospital (with costs absorbed into Radiology Department budget) was performed in 7.6% (39/515) of newly diagnosed breast cancer cases presenting through the breast clinics in 2013, 6.7% (34/505) in 2012, and 6.1% (29/479) in 2011. These numbers were slightly higher if women who presented first at RPH (mainly through BreastScreen assessment service) but were treated elsewhere, were excluded.

As most cases are likely to be in younger women with dense breasts and lobular cancers – comprising about 7% of cancers in women under 50, we estimate the total number of newly diagnosed cases will not exceed 15% of incident cancers, thus 2250 occasions of service per annum.

It is estimated that a maximum of 10% of patients undergoing MRI will require MRI guided biopsy as the lesion will not be visualised by conventional imaging such as targeted ultrasound – a total of less than 225 patients per year (and likely to be significantly less than this with good directed US)

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:

We do not anticipate that this percentage utilisation will change over time.

PART 8 – COST INFORMATION

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

In our original application for extending Item numbers 63487 and 63489, we proposed a fee for breast MRI-guided biopsy of \$1440 based on the current fee for breast MRI plus the extra consumables (\$450, including biopsy gun and clip for placement at the lesion site) and labour costs (\$300, one extra hour of radiologist and radiographer time) required to conduct a biopsy. The ratified ESC Report for this submission (1333_FinalESCReport_Ratified(D15-315730)) commented on the proposed fee of \$1440 'This is in line with the requirements, but a more detailed justification of costs may be required' (page 3, under point 4 'Proposal for public funding'). Since the release of the ESC Report and our resubmission herewith, the two Item Numbers listed below (supported by MSAC – Application 1333) have been updated including MRI guided biopsy of the breast (including gadolinium contrast) – 63489 to \$1440.

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

MRI guided biopsy of the breast (including gadolinium contrast) - 63489

MRI-guided biopsy, 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 a suspicious lesion seen on MRI but not on conventional imaging; and
 - (ii) the lesion is not amenable to biopsy guided by conventional imaging; and
- (d) a repeat ultrasound scan of the affected breast is performed:
 - (i) before the guided biopsy is performed; and
 - (ii) as part of the service under this item (R) (K) (Anaes.)

Fee: \$1,440.00 Benefit: 75% = \$1,080.00 85% = \$1,359.80

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

1 hour

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: Category 5 – Diagnostic imaging services

Proposed item descriptor: MBS [item number (Note: this will be assigned by the Department if listed on the MBS)]

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 either:

(i) that the patient has been diagnosed with a breast cancer and discrepancy exists between clinical assessment and conventional imaging assessment;

(ii) that the patient has a breast lesion which on other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy has not been possible (e.g. possible distortion on only one mammographic view without a sonographic correlate).

Fee: \$[Proposed fee] As per current fee (\$690) for screening MRI in high risk women

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

10 hours

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

- Yes
 No

(b) If no, provide areas of concern:

Describe areas of concern here

55. (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

56. (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