



**Australian Government**

**Department of Health**

# **Application Form**

**(New and Amended**

**Requests for Public Funding)**

**(Version 2.4)**

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.

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.

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# PART 1 – APPLICANT DETAILS

## 1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): The Royal Australian & New Zealand College of Radiologists

Corporation name: The Royal Australian & New Zealand College of Radiologists

ABN:

Business trading name: REDACTED

**Primary contact name:** REDACTED

Primary contact numbers

Business: REDACTED

Email: REDACTED

**Alternative contact name:** REDACTED

Alternative contact numbers

Business: 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

Digital breast tomosynthesis (DBT or 3D mammography)

### 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)

Digital breast tomosynthesis (DBT or 3D mammography) is a radiographic examination of the breast used for screening and diagnosis of breast conditions. It can be used in all situations where conventional 2D mammography is indicated.

In the diagnostic/symptomatic setting, mammography is used to investigate conditions such as inflammation/infection, benign/malignant neoplasms and trauma. It is the test of first choice in women over the age of 35 years and is used as an adjunct test in younger women following ultrasound examination.

In the screening/asymptomatic setting, mammography is used to detect unsuspected cancer. It is the test of choice for women aged over 40 and at population risk of breast cancer, and for younger women at increased risk.

Studies have shown digital breast tomosynthesis when combined with 2D mammography is more sensitive and frequently more specific for breast cancer than 2D mammography alone.

### 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)

Digital breast tomosynthesis (DBT or 3D mammography) is a radiographic procedure used to create a 3D mammographic image of the breast. The digital information is obtained from a series of low dose, angled exposures and is reconstructed to create a 3D image which can be viewed as slices (typically 1mm thick) or in cine mode.

DBT is used in conjunction with either acquired/conventional 2D mammography or synthesised 2D mammography. An acquired 2D image is a 2D image obtained from a standard (2D) radiographic exposure of the breast. A synthesised 2D image is a 2D image created from the 3D information.

A DBT-compatible mammography unit and added DBT software are required to obtain tomosynthesis (DBT or 3D) images. Additional software is also required to create synthesised 2D images.

### 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?

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):

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:**

N/A

**7. 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

**8. 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

**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

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

N/A

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

N/A

Yes

No

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

N/A

(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):

N/A

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

N/A

## 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:

Tomosynthesis is not approved for use by the Australian TGA, however, digital mammography units, which may be modified for tomosynthesis, require approval.

**Type of therapeutic good:** DBT-compatible full field digital mammography unit

14. **Manufacturer's name:** Hologic Inc, Siemen's Healthineers, GE Healthcare, Shimadzu Medical Systems, Planmed Oy, Fujifilm Corporation, IMS, Villa Sistemi Medicali and others with units under development

**Sponsor's name:** N/A

- (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

- (c) 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

- (d) 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

## PART 4 – SUMMARY OF EVIDENCE

(e) 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.	Randomised controlled trial	Digital Mammography versus Digital Mammography Plus Tomosynthesis for Breast Cancer Screening: The Reggio Emilia Tomosynthesis Randomized Trial. Pattacini P	To compare digital mammography (DM) plus digital breast tomosynthesis (DBT) versus DM alone for breast cancer screening. DBT + DM showed 90% more cancers than DM with similar recall rates.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/29869961">https://www.ncbi.nlm.nih.gov/pubmed/29869961</a>	June 2018

2.	Split plot reading study	<p>Can digital breast tomosynthesis perform better than standard digital mammography work-up in breast cancer assessment clinic?</p> <p>Mall S</p>	<p>To compare the efficacy of use of digital breast tomosynthesis (DBT) with standard digital mammography (DM) workup views in the breast cancer assessment clinic.</p> <p>DBT has the potential to increase diagnostic accuracy and simplify the assessment process in the breast cancer assessment clinic.</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pubmed/29846804">https://www.ncbi.nlm.nih.gov/pubmed/29846804</a></p>	<p>May 2018</p>
3.	Prospective population-based screening trial	<p>Digital breast tomosynthesis with synthesized two-dimensional images versus full-field digital mammography for population screening: outcomes from the Verona screening program</p> <p>Caumo F</p>	<p>To examine the outcomes of a breast cancer screening program based on digital breast tomosynthesis (DBT) plus synthesized two-dimensional (2D) mammography compared with those after full-field digital mammography (FFDM)</p> <p>DBT plus synthetic 2D imaging increases cancer detection rates with recall rates comparable to those of FFDM.</p>	<p><a href="https://pubs.rsna.org/doi/10.1148/radiol.2017170745">https://pubs.rsna.org/doi/10.1148/radiol.2017170745</a></p>	<p>April 2018</p>



4.	Retrospective observational study	Comparing diagnostic performance of digital breast tomosynthesis and full-field digital mammography in a hybrid screening environment Giess C	To compare the diagnostic performance of screening digital breast tomosynthesis (DBT) to that of full-field digital mammography (FFDM) in a mixed DBT and FFDM imaging environment. FFDM and DBT recall rates were not significantly different. However, the PPV1 of recalled cases and cancer detection rate were significantly higher with DBT.	<a href="https://www.ajronline.org/doi/abs/10.2214/AJR.17.17983">https://www.ajronline.org/doi/abs/10.2214/AJR.17.17983</a>	October 2017
5.	Retrospective observational study	Clinical implementation of synthesized mammography with digital breast tomosynthesis in a routine clinical practice Freer P	To evaluate implementation of SM + DBT in routine screening. SM + DBT reduces false positives while maintaining cancer detection rates and other desirable outcomes. SM + DBT is more accurate than FFDM alone, and is a desirable alternative to FFDM + DBT, given the added benefit of radiation reduction.	<a href="https://www.researchgate.net/publication/318931013_Clinical_implementation_of_synthesized_mammography_with_digital_breast_tomosynthesis_in_a_routine_clinical_practice">https://www.researchgate.net/publication/318931013_Clinical_implementation_of_synthesized_mammography_with_digital_breast_tomosynthesis_in_a_routine_clinical_practice</a>	August 2017

6.	Prospective population-based screening trial	Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study Bernardi D	To examine whether integrating 3D mammography with either standard 2D mammography or with synthetic 2D images detects more breast cancer than 2D mammography alone, to potentially reduce radiation burden from combined 2D plus 3D acquisitions. More cases of breast cancer detected but increased percentage of false-positive recalls in sequential screen-reading.	<a href="https://www.researchgate.net/publication/304357553_Breast_cancer_screening_with_tomosynthesis_3D_mammography_with_acquired_or_synthetic_2D_mammography_compared_with_2D_mammography_alone_STORM-2_A_population-based_prospective_study?ev=publicSearchHeader&amp;sg=-3fXDEPwBYeFbxNkEtDvA7v6hQSNpqhMkOPUtUKYzAmzRV-d_V01Jcm7IEmk-4JFGw7ypB4I_wCk2CU">https://www.researchgate.net/publication/304357553_Breast_cancer_screening_with_tomosynthesis_3D_mammography_with_acquired_or_synthetic_2D_mammography_compared_with_2D_mammography_alone_STORM-2_A_population-based_prospective_study?ev=publicSearchHeader&amp;sg=-3fXDEPwBYeFbxNkEtDvA7v6hQSNpqhMkOPUtUKYzAmzRV-d_V01Jcm7IEmk-4JFGw7ypB4I_wCk2CU</a>	August 2016
7.	Retrospective observational study	Effectiveness of digital breast tomosynthesis compared with digital mammography: outcomes analysis from 3 years of breast cancer screening McDonald E	To determine whether improved outcomes observed after implementation of DBT screening are sustainable over time and to evaluate the effect of more than 1 DBT screening at the individual level. Digital breast tomosynthesis screening outcomes sustainable, with recall reduction, increased cancer cases, and decline in interval cancers	<a href="http://assets.krebsliga.ch/downloads/effectiveness_of_digital_breast_tomosynthesis_compared_with_digital_mammography.pdf">http://assets.krebsliga.ch/downloads/effectiveness_of_digital_breast_tomosynthesis_compared_with_digital_mammography.pdf</a>	June 2016

8.	Retrospective observational study	Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: a cohort study within the PROSPR consortium Conant E	To assess if DBT is associated with improved screening outcomes based on follow-up data from tumor registries or pathology. Our data support implementation of DBT screening based on increased cancer detection, reduced recall, and no difference in false negative screening examinations.	<a href="https://www.semanticscholar.org/paper/Breast-cancer-screening-using-tomosynthesis-in-with-Conant-Beaber/cc335c9854edffca8e491d324f8383d56b12a0f9">https://www.semanticscholar.org/paper/Breast-cancer-screening-using-tomosynthesis-in-with-Conant-Beaber/cc335c9854edffca8e491d324f8383d56b12a0f9</a>	February 2016
9.	Prospective population-based screening trial <sup>^</sup>	Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: results from the Malmo breast tomosynthesis screening trial, a population-based study Lang K	To assess the performance of one-view digital breast tomosynthesis (DBT) in breast cancer screening. Our results suggest that one-view DBT might be feasible as a stand-alone screening modality.	<a href="http://portal.research.lu.se/portal/en/publications/performance-of-oneview-breast-tomosynthesis-as-a-standalone-breast-cancer-screening-modality-results-from-the-malmoe-breast-tomosynthesis-screening-trial-a-populationbased-study(e54d3b07-687a-4a70-b671-c95332ad5eb2)/export.html">http://portal.research.lu.se/portal/en/publications/performance-of-oneview-breast-tomosynthesis-as-a-standalone-breast-cancer-screening-modality-results-from-the-malmoe-breast-tomosynthesis-screening-trial-a-populationbased-study(e54d3b07-687a-4a70-b671-c95332ad5eb2)/export.html</a>	January 2016

10.	Retrospective observational study	Clinical performance metrics of 3D digital breast tomosynthesis compared with 2D digital mammography for breast cancer screening in community practice. Greenberg J	To assess the clinical performance of combined 2D-3D digital breast tomosynthesis DBT, compared with 2D digital mammography (DM) alone for screening mammography in a community-based radiology practice. Mammography screening with 3D DBT yielded lower recall rates, an increased CDR for cancer overall and for invasive cancer, compared with 2D DM.	<a href="https://www.sciencedirect.com/science/article/pii/S0960977616000072">https://www.sciencedirect.com/science/article/pii/S0960977616000072</a>	September 14
11.	Retrospective observational study	Breast cancer screening using tomosynthesis in combination with digital mammography. Friedewald S	To determine if mammography combined with tomosynthesis is associated with better performance of breast screening programs in the United States. Addition of tomosynthesis was associated with a decrease in recall rate and an increase in cancer detection rate. Further studies are needed to assess the relationship to clinical outcome.	<a href="https://jamanetwork.com/journals/jama/fullarticle/1883018">https://jamanetwork.com/journals/jama/fullarticle/1883018</a>	June 2014

12.	Prospective population-based screening trial	Two view breast tomosynthesis screening with synthetically reconstructed projection images: comparison with digital breast tomosynthesis with full-field digital mammographic images. Skaane P	To compare the performance of two versions of reconstructed two-dimensional (2D) images in combination with digital breast tomosynthesis (DBT) versus the performance of standard full-field digital mammography (FFDM) plus DBT. The combination of current reconstructed 2D images and DBT performed comparably to FFDM plus DBT and is adequate for routine clinical use when interpreting screening mammograms.	<a href="https://pubs.rsna.org/doi/abs/10.1148/radiol.13131391">https://pubs.rsna.org/doi/abs/10.1148/radiol.13131391</a>	January 2014
13.	Prospective population-based screening trial	Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. Ciatto S	To investigate the effect of integrated 2D and 3D mammography in population breast cancer screening. Integrated 2D and 3D mammography improves breast-cancer detection and has the potential to reduce false positive recalls. Randomised controlled trials are needed to compare integrated 2D and 3D mammography with 2D mammography.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/23623721">https://www.ncbi.nlm.nih.gov/pubmed/23623721</a>	June 2013

14.	Retrospective observational study	Implementation of breast tomosynthesis in a routine screening practice: an observational study. Rose S	To assess the changes in performance measures after the introduction of tomosynthesis systems into our clinical practice. The introduction of breast tomosynthesis into our practice was associated with a significant reduction in recall rates and a simultaneous increase in breast cancer detection rates.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/?term=Implementation+of+breast+tomosynthesis+in+a+routine+screening+practice%3A+an+observational+study.">https://www.ncbi.nlm.nih.gov/pubmed/?term=Implementation+of+breast+tomosynthesis+in+a+routine+screening+practice%3A+an+observational+study.</a>	June 2013
15.	Prospective population-based screening trial	Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program. Skaane P	To assess cancer detection rates, false-positive rates, positive predictive values, and type of cancers detected with use of digital mammography alone and combined with tomosynthesis in a large prospective screening trial. Use of tomosynthesis resulted in a significantly higher cancer detection rate and enabled the detection of more invasive cancers.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/?term=Comparison+of+digital+mammography+alone+and+digital+mammography+plus+tomosynthesis+in+a+population-based+screening+program.">https://www.ncbi.nlm.nih.gov/pubmed/?term=Comparison+of+digital+mammography+alone+and+digital+mammography+plus+tomosynthesis+in+a+population-based+screening+program.</a>	April 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.

(f) 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.	Prospective population-based screening trial	BreastScreen Victoria tomosynthesis screening trial, Maroondah pilot: Preliminary outcomes (registered trial: ACTRN12617000947303)	Australia’s first pilot trial of tomosynthesis for screening commenced in BreastScreen Victoria, at Maroondah BreastScreen in August 2017. This prospective trial is aiming to recruit 5,000 women screened with tomosynthesis (tomosynthesis acquisition, synthesized 2D images) to assess the feasibility of tomosynthesis screening and to estimate screen-detection measures for this technology.	NA	Abstract published at BreastScreen Australia Conference April 2018

\* 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):**

*Medical Imaging specialists delivering the service:*

The Royal Australian and New Zealand College of Radiologists (RANZCR)  
Australian Diagnostic Imaging Association (ADIA)  
Australian Institute of Radiography (AIR)  
Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)

*Professionals requesting the service:*

The Royal Australian College of General Practitioners (RACGP)  
The Royal Australasian College of Surgeons (RACS)  
The Royal Australasian College of Physicians (RACP)  
Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)  
The Australasian Society of Breast Physicians (ASBP)

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

N/A – same as above

- 21. 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)  
National Breast Cancer Foundation (NBCF)  
Cancer Councils – Australia, all states and territories

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

**Manufacturers which have DBT mammography units on the market:**

Hologic Inc  
Siemen's Healthineers  
GE Healthcare  
Shimadzu Medical Systems  
Planmed Oy  
Fujifilm Corporation  
IMS  
Villa Sistemi Medicali

- 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  
Telephone number(s): REDACTED  
Email address: REDACTED  
Justification of expertise: REDACTED

Name of expert 2: REDACTED



Telephone number(s): REDACTED  
Email address: REDACTED  
Justification of expertise: REDACTED

Name of expert 3: REDACTED  
Telephone number(s): REDACTED  
Email address: REDACTED  
Justification of expertise: 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

- 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:**

Breast imaging with mammography is carried out to investigate symptomatic and asymptomatic women (and less frequently symptomatic men) to identify malignant and benign diseases. Benign conditions of the breast are not life threatening but most require breast imaging for diagnosis and for exclusion of malignancy. For both symptomatic and asymptomatic patients, early detection of breast cancer results in reduced mortality and morbidity. BreastScreen Australia offers population screening for women aged 40 years or more and is targeted to women aged 50 to 74 years. For women at increased risk of breast cancer (e.g. women with a family history or previous history of the disease - see below), mammography screening is used across a wider age range and is delivered by both private and public facilities.

The following data on breast cancer is taken from: Australian Institute of Health and Welfare & Cancer Australia 2012. Breast cancer in Australia: an overview. Cancer series no. 71. Cat. no. CAN 67. Canberra: AIHW.

### *Incidence and Mortality*

In 2008 Breast cancer was the most common cancer in females, representing 28% of all reported cancers in females, with the majority (69%) of cases diagnosed in females aged 40–69. The number of new breast cancers more than doubled between 1982 (5,310 cases) and 2008 (13,567). The sharp increase in age-standardised incidence rate between 1990 and 1995 is most likely due to the introduction of the national breast cancer screening program. The rate has remained fairly stable since 1995.

A total of 2,680 females died from breast cancer in 2007, making it the second most common cause of cancer-related death for Australian females after lung cancer (2,911 deaths). The age standardised mortality rate for breast cancer decreased between 1994 and 2007 by 29%.

### *Known risk factors*

For females, the main factors associated with an increased risk of breast cancer are:

- Family history of breast cancer
- Breast conditions—females diagnosed with invasive breast cancer have an increased risk of developing a new cancer in the other breast or in another part of the same breast. Research has also shown that females diagnosed with certain pre-invasive breast conditions including DCIS and LCIS have an increased risk of developing invasive breast cancer. Further, females with a high degree of breast density have higher risk of invasive breast cancer compared with females with lower breast density.
- Hormonal factors
- Child-bearing history
- Personal and lifestyle factors

### *Survival and Prevalence*

In the period 2006–2010 in Australia, 5-year relative survival from breast cancer in females was 89% for all ages combined.

At the end of 2008 in Australia more than 57,300 females were alive who had been diagnosed with breast cancer within the previous 5 years.

At the end of 2008, 159,325 females were alive who had been diagnosed with breast cancer in the previous 27 years. This equated to 147 per 10,000 females.

#### *BreastScreen Australia and MBS Mammography*

In the 2009–2010 two-year period 1,710,312 women participated in BreastScreen Australia.

In 2011 354,340 Medicare Benefits Scheme (MBS)-funded mammography services were provided to women, representing 0.2% of all services to women subsidised by the MBS.

- 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:**

#### *Patient characteristics for eligibility*

Current Medicare Benefits Scheme funding for 2D mammography of both or one breast is available for women (and men) with symptoms or signs of possible malignancy and for those at increased risk of breast malignancy due to family history or previous history of breast cancer.

<http://www9.health.gov.au/mbs/search.cfm?q=59300&Submit=&sopt=l>

The proposed medical service, digital breast tomosynthesis (DBT or 3D mammography), is appropriate for use in all situations where 2D mammography is currently indicated.

#### *Current and proposed patient investigation, management and referral*

Prior to the use of mammography, patients are investigated with clinical history and examination by their general practitioner or a breast clinical specialist. Referral for mammography is based on the identification of symptoms or signs of possible malignancy on clinical examination, or on the identification of a history of previous breast malignancy or of a family history of the disease. Patient management is based on the combined clinical and imaging results.

As proposed, no change in investigation or referral or management is required due to the introduction of digital breast tomosynthesis.

- 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):**

Patient presents to general practitioner or clinical specialist

↓

Clinical history taken → a history of previous breast malignancy or of a family history of the disease → referral for mammography (if age appropriate)

↓

Clinical examination performed → symptoms or signs of possible malignancy identified → referral for mammography (if age appropriate)

#### **PART 6b – INFORMATION ABOUT THE INTERVENTION**

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

#### *Image acquisition*

Digital breast tomosynthesis (DBT or 3D mammography) is a radiographic procedure used to create a 3D mammographic image of the breast. Its acquisition requires a DBT-compatible mammography unit with activated DBT software. DBT images can be taken in any projection in which a conventional 2D image can be taken. The digital DBT information is obtained from a series of low dose, angled radiographic exposures and is reconstructed to create a 3D image.

There are no significant differences in conventional 2D or DBT mammography from the patient or radiographer perspective.

*Image storage and display*

3D images can be stored and displayed using any radiology PACS system with current software.

*Image review*

The DBT or 3D images are reviewed on a radiology workstation and displayed as slices (typically 1mm) or in cine mode. This requires high resolution monitors suitable for digital mammography and 'current' display software.

Almost universally the 3D images are reviewed alongside 2D images of the breast – either conventionally acquired 2D images or synthesised 2D images which have been created from the 3D slice information using additional software.

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

N/A

**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?**

N/A

**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):**

The limitations for 3D mammography are the same as those for 2D with the exception of radiation dosage.

The dose required for 3D images is generally slightly greater than that of a conventional 2D image. If both 3D and 2D images are acquired there is approximately a doubling of the radiation exposure but this is within RANZCR accreditation requirements. If 2D images are synthesised from the 3D data then the additional exposure is no longer required and patient dosage is reduced to that of a single exposure.

**31. 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:**

N/A

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

Radiologists and radiographers

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

N/A

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

N/A

**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:**

Radiologists typically undergo additional training, as part of professional development, for 3D image interpretation, and the US FDA has an eight-hour training requirement. When compared with 2D interpretation, additional time (up to two times) is required in the viewing and interpretation of the 3D images.

Application training in equipment usage is required for radiographers prior to taking 3D mammograms. However patient positioning remains the same as for 2D mammography.

**36. (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:**

Most patients requiring mammography are ambulant and therefore the procedure can be carried out in the public or private in-patient or outpatient settings.

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

- 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):**

For the usage of 3D mammography there are no changes required when compared with the current delivery of 2D mammography services.

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

***59303 MAMMOGRAPHY OF ONE BREAST***

MAMMOGRAPHY OF ONE BREAST, if:

- (a) the patient is referred with a specific request for a unilateral mammogram; and  
(b) there is reason to suspect the presence of malignancy because of:  
(i) the past occurrence of breast malignancy in the patient or members of the patient's family;  
or  
(ii) symptoms or indications of malignancy found on an examination of the patient by a medical practitioner (R)

***59300 MAMMOGRAPHY OF BOTH BREASTS***

MAMMOGRAPHY OF BOTH BREASTS, if there is a reason to suspect the presence of malignancy because of:

- (i) the past occurrence of breast malignancy in the patient or members of the patient's family; or  
(ii) symptoms or indications of malignancy found on an examination of the patient by a medical practitioner. Unless otherwise indicated, mammography includes both breasts (R)

***60100 TOMOGRAPHY OF ANY REGION (R) (Anaes.)***

**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):**

Following mammography examination, management is based on the combined results of clinical history and examination, mammography and other imaging. Tissue biopsy or surgery may be required.

No changes to the current clinical management pathways will be required due to the introduction of tomosynthesis.

**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:**

Current practice is acquired 2D digital mammography. The proposed DBT or 3D mammography can be used either in conjunction with acquired 2D mammography (current comparator) or in place of it with 2D images created from the 3D data (synthesised 2D).

Given the literature evidence for additional sensitivity and specificity of DBT or 3D combined with 2D mammography when compared with 2D mammography alone and given the equivalency of synthesised 2D and acquired 2D mammography, it is possible that over time DBT or 3D imaging with synthesised 2D imaging will completely replace acquired 2D imaging.

**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):**

The introduction of the proposed DBT or 3D mammography is not expected to result in any change in current clinical management pathways.

**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):**

**Benefits**

Published literature (based on a limited number of manufacturers) strongly suggests that the combined use of 2D mammography and DBT or 3D mammography generally results in greater sensitivity and often greater specificity than are achieved by use of current (acquired) 2D digital mammography alone. These outcomes equate to improved diagnostic accuracy.

Published literature (based on a limited number of manufacturers) strongly suggests that the diagnostic outcomes from synthesised 2D mammography and from acquired 2D mammography are equivalent. The use of synthesised 2D results in reduced radiation exposure to the patient.

**Harms**

Increased dose is a potential harm. Optimal clinical practice requires 3D mammography to be used concurrently with 2D images. If DBT or 3D mammography is used with acquired 2D mammography there is an increased, approximately doubled, radiation exposure to the breast. However published studies have shown that, for some manufacturers, outcomes obtained from 3D combined with synthesised 2D images (created from 3D data) are equivalent or not significantly different from those obtained from 3D combined with acquired 2D images. The use of DBT or 3D with synthesised 2D images reduces radiation exposure, which is then similar to that resulting from current acquired 2D alone.

Increased overdiagnosis is a potential harm of the proposed DBT or 3D mammography in screening. Overdiagnosis is the diagnosis by screening of malignancies that would not otherwise have been diagnosed in the woman’s lifetime – or would not have been diagnosed in the absence of screening. The magnitude of this problem is controversial for 2D mammography screening and has not yet been evaluated for combined 2D and 3D mammography screening.

**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:**

**Safety Outcomes:**

Increased radiation dose  
increased overdiagnosis

**Clinical Effectiveness Outcomes:**

increased sensitivity  
increased specificity  
overall improved diagnostic accuracy



## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

The age standardised rate of breast cancer in 2008 was 115.4 per 100,000 females (standardised to the Australian population as at 30 June 2001) REF: Australian Institute of Health and Welfare & Cancer Australia 2012. Breast cancer in Australia: an overview. Cancer series no. 71. Cat. no. CAN 67. Canberra: AIHW.

Representation of numbers suggested above are not applicable. RANZCR suggests the medical rebate numbers for last 12-24 months be retrieved for both 2D mammography and tomosynthesis. In real terms, the expected projection of tomosynthesis numbers in future will sit somewhere between these two numbers.

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

Typically once only for the majority of symptomatic patients

Typically once per year for assessment of women at increased risk because of a personal or family history of breast cancer

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

Typically one year only for the majority of symptomatic patients

Typically annually for life for women at increased risk

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

Estimated at 500,000 or greater

### **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:**

DBT is currently being used in clinical practice. MBS item number 60100 has been used for DBT but not exclusively for DBT. Use of this item number has increased over recent years as follows:

2011/12 – 33,593

2012/13 – 40,521

2013/14 – 86,955

2014/15 – 197,953

2015/16 – 333,831

2016/17 – 423,066

## PART 8 – COST INFORMATION

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

RANZCR recommends a fee of \$225 for DBT of both breasts and \$. We understand that the current interim fee is \$202 and that this amount has been based on the summation of the previous mammography fee, and the previous tomography fee. We note that the previous tomography fee is a legacy item and not directly comparable to current breast tomosynthesis technology. More importantly, mammography is underfunded and has an inadequate Medicare rebate which has been frozen since 1998. Diagnostic mammography has one of the lowest bulk billing rates of all imaging procedures (around 50%), making it very difficult for patients to access this service if they cannot afford to pay a sometimes-significant gap. Therefore, it is recommended that a higher Medicare rebate of \$225 be inserted. RANCR believes that this will improve access to this much needed service.

**51. 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.**

**RANZCR suggests changes to the current interim item descriptor when DBT is listed on the MBS Schedule which are noted in red.**

### **One Breast**

Three dimensional tomosynthesis of one breast, if there is reason to suspect the presence of **breast disease** or malignancy because of:

- a) the past occurrence of breast malignancy in the patient or members of the patient's family; or
- b) symptoms or indications of **breast disease or suspected malignancy** found on examination of the patient by a medical practitioner

*Fee: \$128*

### **Both Breasts**

Three dimensional tomosynthesis of both breasts, if there is reason to suspect the presence of **breast disease** or malignancy because of:

- a) the past occurrence of breast malignancy in the patient or members of the patient's family; or
- b) symptoms or indications of **breast disease or suspected malignancy** found on examination of the patient by a medical practitioner

*Fee: \$225*

## PART 9 – FEEDBACK

The Department is interested in your feedback.

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

6 months

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

Yes

No

**(b) If no, provide areas of concern:**

Repetitive questions.

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

Yes

No

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

**55. (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