



Australian Government

Medical Services Advisory Committee

## Public Summary Document

### ***Application 1682 - Amendment to MBS Item 63464 – MRI for the detection of breast cancer in asymptomatic high-risk patients***

**Applicant:** Department of Health

**Date of MSAC consideration:** MSAC 83rd Meeting, 25-26 November 2021

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

#### **1. Purpose of application**

To consider the financial implications of a recommendation from the Medicare Benefits Schedule (MBS) Review Taskforce - Diagnostic Imaging Clinical Committee (DICC) to amend MBS item 63464 to include asymptomatic patients at high risk of developing breast cancer aged under 60 years.

#### **2. MSAC's advice to the Minister**

After considering the estimated utilisation and financial impact of the MBS Review Taskforce - DICC's recommendation, MSAC supported amending MBS item 63464 to include asymptomatic patients at high risk of developing breast cancer aged less than 60 years. MSAC considered there is an established clinical need for the service in the proposed population. MSAC advised that the financial implications to the MBS as a result of amending MBS item 63464 to include this high-risk population with high clinical need were reasonable.

MSAC supported the following MBS item:

*MBS item 63464*

*MRI—scan of both breasts for the detection of cancer, if a dedicated breast coil is used, the request for the scan identifies that the person is asymptomatic and is younger than 60 years of age, and the request for the scan identifies:*

- (l) that the patient is at high risk of developing breast cancer, due to one of the following:*
  - (a) genetic testing has identified the presence of a high risk breast cancer gene mutation either in them or in their first degree relative; or*
  - (b) has one first or second degree relative diagnosed with breast cancer at age 45 years or younger, and another first or second degree relative on the same side of the family with bone or soft tissue sarcoma at age 45 years or younger; or*
  - (c) has a personal history of breast cancer prior to age 50 years; or*
  - (d) has a personal history of mantle radiation therapy; or*

(e) has a lifetime risk estimation of > 30% or a 10-year absolute risk estimation > 5% using the Tyrer-Cuzick (IBIS Risk Evaluator) algorithm version 8 or later.

The service cannot be performed in conjunction with 55076 or 55079

Benefits are payable on one occasion only in any 12 month period

Fee: \$690.00 Benefit: 75% = \$517.50 85% = \$605.30

#### Consumer summary

This application was in response to a recommendation from the Medicare Benefits Schedule (MBS) Review Taskforce - Diagnostic Imaging Clinical Committee (DICC) to increase the cut-off age of people who are eligible to have magnetic resonance imaging (MRI) if they are at high risk of developing breast cancer.

MRI uses a powerful magnetic field, radio waves and a computer to produce detailed pictures of the inside of the body. People who are at high risk of breast cancer but have no symptoms are currently funded under the MBS to have an MRI to check for breast cancer every year up until the age of 50 years (MBS item 63464), in addition to a mammogram (x-ray imaging of breast tissue). At age 50, these people can continue to have mammograms.

As part of a recent review of the MBS, the MBS Review Taskforce-DICC recommended changing MBS item 63464 to increase the age cut-off to less than 60 years. This is because most people with genetic risk factors for breast cancer will develop cancer before age 60. Cancers caused by one type of genetic mutation (called *BRCA2*) are most commonly diagnosed between age 50 and age 60.

MSAC discussed the extra number of people who would be accessing a breast MRI each year if the age cut-off was increased from less than 50 years to less than 60 years, and the cost to the MBS of these extra scans. MSAC considered the extra cost to the MBS to fund annual breast MRI for women aged 50-59 years at high-risk of breast cancer was reasonable.

#### MSAC's advice to the Commonwealth Minister for Health

MSAC supported amending MBS item 63464 to increase the age cut-off to 60 years as MSAC considered the additional costs to the MBS fund breast MRI in this population with high risk of breast cancer and high clinical need was reasonable.

### 3. Summary of consideration and rationale for MSAC's advice

MSAC noted the MBS Review Taskforce - DICC recommended amending MBS item 63464, for magnetic resonance imaging (MRI) for the detection of breast cancer in asymptomatic high-risk patients, to increase the age cut-off for the eligible population from less than 50 years to less than 60 years. Following the advice of the MSAC Executive, application 1682 seeks MSAC advice on the potential utilisation and financial impact to the MBS as a result of the proposed amendment to MBS item 63464, and whether MSAC would support the amendment.

MSAC noted the DICC 2018 Breast Imaging Report<sup>1</sup> cited Kuchenbaecker et al. (2017)<sup>2</sup> which reported that for people with a high-risk breast cancer gene mutation, most breast cancers occur before the age of 60 years. In particular, peak incidence of breast cancer occurs at age 41-50 years for people with *BRCA1* mutations and 51-60 years for *BRCA2*. The DICC also indicated that the cost-effectiveness of MRI decreases after age 60 due to the reduction in breast density

<sup>1</sup> MBS Review Taskforce. Report from the Diagnostic Imaging Clinical Committee – Breast Imaging. 2018.

<sup>2</sup> Kuchenbaecker, K. et al. (2017). *Journal of the American Medical Association*, 317(23): 2402-16.

related to menopause, which makes mammography more appropriate in people aged over 60 years. MSAC noted the DICC had also recommended that ultrasound at the same time as MRI is not necessary, but can be done as a targeted examination if an abnormality is detected. MSAC recalled that it had previously considered the safety and effectiveness of breast MRI, noting there were no safety issues regarding the dose of ionising radiation and there are very small risks associated with the use of gadolinium-based contrast agents (anaphylaxis, renal failure and nephrogenic systemic fibrosis).

MSAC noted the estimated financial impact to the MBS as a result of amending MBS item 63646 was modelled using a market-share approach. The analysis assumed that the referral pattern for breast MRI is well established, and that people aged 45–49 years who currently have MRI would continue to have MRI until age 59 if it was MBS funded. MSAC noted this means the current utilisation numbers could be used to model the number of people aged 50–59 years who would have breast MRI. MSAC considered this may represent a slight overestimate, as some of these people would have a mastectomy or die before age 60, but considered this assumption was reasonable. MSAC also noted the assumption that other changes to the item descriptor relating to the definition of “high risk” would not affect utilisation.

MSAC noted the estimated utilisation of breast MRI using the revised MBS item descriptor was an additional 3,630 patients in year 1, increasing to 4,858 patients in year 6 (assuming 100% uptake in each year, based on an average 6% annual increase from the previous 5 years of data). This would result in a total net cost to the MBS of \$14,464,871 million over 6 years. MSAC noted the sensitivity analyses explored the uptake rate, growth in number of eligible patients, ultrasound use, 2D vs 3D mammograms, and cost of services after co-payments. The financial estimates were not markedly sensitive to any of these parameters, and each of these analyses resulted in relatively small changes to the additional cost to the MBS over 6 years except for the use of 3D versus 2D mammograms. MSAC noted asymptomatic high-risk women aged 50-59 years will undergo a mammogram irrespective of whether an MRI is funded for this population. On this basis, MSAC considered the relevant impact to the MBS is the additional costs for the MRI in this population leading to a net cost to the MBS of approximately \$17,136,091 over six years. Overall, MSAC considered the estimated additional cost to the MBS to fund annual breast MRI for women aged 50-59 years at high-risk of breast cancer was reasonable.

MSAC also noted that general practitioners cannot order an MRI on the MBS for this purpose, and that information and education is needed among people at high risk of breast cancer, as well as ensuring these patients can access relevant specialists.

## 4. Background

In 2006, MSAC considered and supported breast MRI for asymptomatic patients at high risk of developing breast cancer aged less than 50 years ([MSAC application 1098](#)). In 2014, MSAC reviewed MBS item 63464 ([MSAC application 1098.1](#)).

In 2018, the MBS Review Taskforce - DICC recommended amending MBS item 63464 for asymptomatic patients at high risk of developing breast cancer to increase the age cut-off for the eligible population from <50 to <60 years (Recommendation 5, pg 31 of [MBS Review Taskforce Report from the DICC – Breast Imaging – 2018](#)).

The DICC recommended amendment to MBS item 63464 was presented to the MSAC Executive in 2021. The MSAC Executive considered that a formal HTA evaluation was not required but, due to the change in patient population, information on the potential utilisation and net financial impact to the MBS should be presented to MSAC.

## 5. Prerequisites to implementation of any funding advice

MRI devices and contrast agents for clinical MRI are included on the Australian Register of Therapeutic Goods (ARTG).

## 6. Proposal for public funding

In response to the DICC – Breast Imaging Recommendation 5, it is proposed that the MBS item number 63464 for MRI in asymptomatic patients at high risk of developing breast cancer be amended to extend the patient age from less than 50 years of age to less than 60 years of age.

The proposed amendments to MBS item 63464 to increase the age cut-off and updates to update the definition of “high risk” (shown in red text) are presented in Table 1.

**Table 1 Presentation of amended MBS item 63464**

Category 5 - DIAGNOSTIC IMAGING SERVICES
<p>MBS item 63464</p> <p>MRI—scan of both breasts for the detection of cancer, if a dedicated breast coil is used, the request for the scan identifies that the person is asymptomatic and is younger than <del>50</del> 60 years of age, and the request for the scan identifies:</p> <ul style="list-style-type: none"> <li>(l) that the patient is at high risk of developing breast cancer, due to one of the following: <ul style="list-style-type: none"> <li>(a) genetic testing has identified the presence of a high risk breast cancer gene mutation either in them <b>or in their first degree relative</b>; or</li> <li>(b) has one first or second degree relative diagnosed with breast cancer at age 45 years or younger, and another first or second degree relative on the same side of the family with bone or soft tissue sarcoma at age 45 years or younger; or</li> <li>(c) <b>has a personal history of breast cancer prior to age 50 years; or</b></li> <li>(d) <b>has a personal history of mantle radiation therapy; or</b></li> <li>(e) <b>has a lifetime risk estimation of &gt; 30% or a 10-year absolute risk estimation &gt; 5% using the Tyrer-Cuzick (IBIS Risk Evaluator) algorithm version 8 or later.</b></li> </ul> </li> </ul> <p><i>The service cannot be performed in conjunction with 55076 or 55079</i></p> <p><i>Benefits are payable on one occasion only in any 12 month period</i></p>
Fee: \$690.00 Benefit: 75% = \$517.50 85% = \$605.30

Note: proposed amendments shown in red text

## 7. Population

The proposed patient population is asymptomatic patients at high risk of developing breast cancer who are aged less than 60 years and meet all other eligibility criteria for MBS item 63464.

MBS item 63464 specifies high risk of developing breast cancer as:

- (a) that the patient is at high risk of developing breast cancer, due to one of the following:
  - (i) 3 or more first or second degree relatives on the same side of the family diagnosed with breast or ovarian cancer;
  - (ii) 2 or more first or second degree relatives on the same side of the family diagnosed with breast or ovarian cancer, if any of the relatives has been diagnosed with bilateral breast cancer, had onset of breast cancer before the age of 40 years, had onset of ovarian cancer before the age of 50 years, has been diagnosed with breast and

- ovarian cancer (at the same time or at different times), has Ashkenazi Jewish ancestry or is a male relative who has been diagnosed with breast cancer;
- (iii) one first or second degree relative diagnosed with breast cancer at age 45 years or younger, and another first or second degree relative on the same side of the family with bone or soft tissue sarcoma at age 45 years or younger; or
- (b) that genetic testing has identified the presence of a high risk breast cancer gene mutation (R).

## 8. Comparator

The comparator is the current MBS funded surveillance strategy for women aged 50 years and older who are asymptomatic and at high risk of breast cancer: annual mammography (MBS item 59300 (2D) and 59302(3D)), with or without breast ultrasound (MBS item 55070).

## 9. Financial/budgetary impacts

A market-share approach was used to estimate the financial implications of funding MRI for patients aged 50 to 59 years at high risk of developing breast cancer. The estimated utilisation was based on the following assumptions:

- 100% of high-risk patients (who access MBS item 63464 when aged less than 50) would opt to continue to receive an annual MRI if it was MBS funded up until age 59.
- 6% annual growth based on rate of growth for MBS item 63464 over the past 5 years.
- Patients who are 50 years or older who are currently unable to access breast MRI under MBS item 63464 switch back to annual mammograms +/- ultrasound only.
- MRI with mammogram is recommended annually based on Australian guidelines:
  - [eviQ Guidelines](#) recommend that women in this age group have annual mammograms and consider annual breast MRI for dense breast tissue (Cancer Institute NSW)<sup>3</sup>
  - 1 out of 3 women older than 50 years have denser breast tissue (Breast Screen Australia)<sup>4</sup>

The number of mammograms won't change but the type of mammogram may change (i.e. MRI with 2D mammogram or 3D mammogram when unable to access breast MRI)
  - The estimated number of MRI services and costs for the first six years is presented in Table 2.

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<sup>3</sup> [Cancer Institute NSW eviQ. Breast cancer \(high risk with no family history of ovarian cancer\) – risk management \(female\). NSW Government](#)

<sup>4</sup> [Department of Health. Breast Density and Screening: Position Statement. Breast Screen Australia.](#)

**Table 2 Net financial implications of MRI in high-risk breast cancer**

<b>Change in use and cost of other health technologies</b>						
<b>Parameter</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>	<b>Year 6</b>
<b>Utilisation estimates</b>						
<b>Expanded eligible patients to include high risk patients aged 50-59</b>						
Number eligible	3,630	3,848	4,079	4,323	4,583	4,858
MRI Uptake Year 1	100%	100%	100%	100%	100%	100%
Receive MRI breast services	3,630	3,848	4,079	4,323	4,583	4,858
Mammogram 2D	3,630	3,848	4,079	4,323	4,583	4,858
Ultrasound <sup>a</sup>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Current high-risk patients aged 50 to 59</b>						
Mammogram 3D	3,630	3,848	4,079	4,323	4,583	4,858
Ultrasound <sup>a</sup>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Financial estimates</b>						
<b>Current high-risk patients aged 50 to 59</b>						
Mammogram 3D <sup>b</sup>	\$678,556	\$719,269	\$762,425	\$808,171	\$856,661	\$908,061
Ultrasound <sup>a</sup>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Sub Total</b>	<b>\$678,556</b>	<b>\$719,269</b>	<b>\$762,425</b>	<b>\$808,171</b>	<b>\$856,661</b>	<b>\$908,061</b>
<b>Expanded breast MRI to include high risk patients aged 50 to 59</b>						
MRI Breast MBS	\$2,456,675	\$2,604,076	\$2,760,320	\$2,925,939	\$3,101,496	\$3,287,585
Mammogram 2D <sup>e</sup>	\$295,603	\$313,339	\$332,139	\$352,068	\$373,192	\$395,583
Ultrasound <sup>a</sup>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Sub Total <sup>c</sup></b>	<b>\$2,752,278</b>	<b>\$2,917,414</b>	<b>\$3,092,459</b>	<b>\$3,278,007</b>	<b>\$3,474,687</b>	<b>\$3,683,169</b>
<b>Net cost to MBS <sup>d</sup></b>	<b>\$2,073,722</b>	<b>\$2,198,145</b>	<b>\$2,330,034</b>	<b>\$2,469,836</b>	<b>\$2,618,026</b>	<b>\$2,775,108</b>

Source: Table 1, pg of MSAC 1682 Assessment Report

Abbreviations: MBS, Medical Benefits Schedule; MRI, magnetic resonance imaging

<sup>a</sup> Mammograms in some women with dense breast may be inconclusive and require additional ultrasound of both breasts. The base case assumes that the Ultrasound requirement is the same for MRI & 2D mammogram and 3D mammogram alone. This assumption was tested in the sensitivity analysis where the MRI & 2D mammogram had a 10% lower Ultrasound rate. N/A only applies to the sensitivity analysis; US was +/- = no difference between current and new high-risk group in ultrasound, therefore not assessed

<sup>b</sup> Current 3D mammogram cost MBS item 59302 average benefit paid \$186.93.

<sup>c</sup> Proposed listing MRI and 2D mammogram

<sup>d</sup> Net cost to MBS is the difference in cost is calculated by subtracting the proposed listing, MRI and 2D mammogram minus the current listing applying 3D mammogram.

<sup>e</sup> Current 2D mammogram cost MBS item 59300 average benefit paid \$81.43

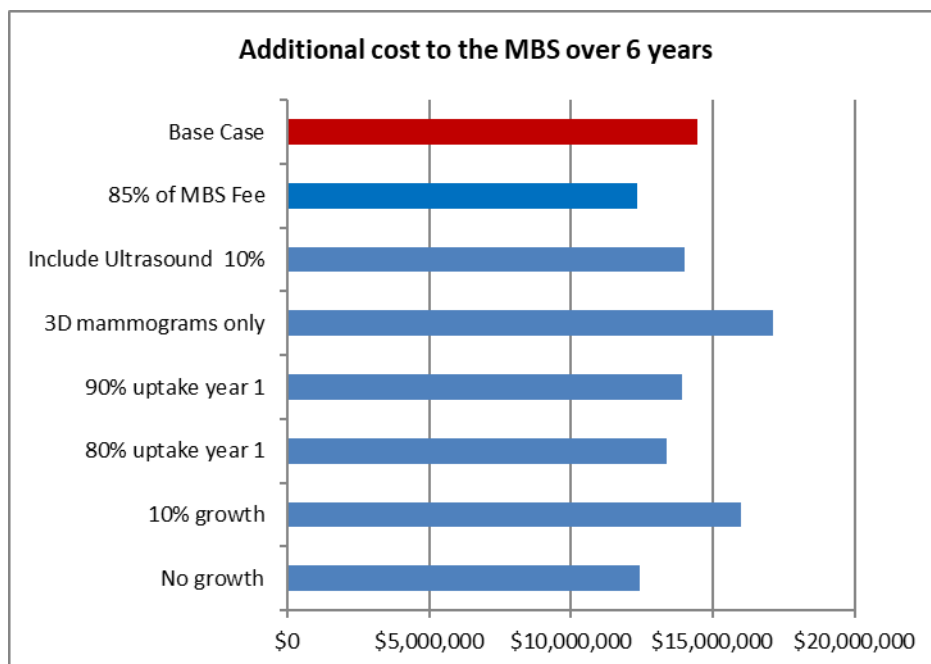
The financial impact of increasing the age cut-off from less than 50 years to less than 60 years for MRI use in high-risk patients is \$2,752,278 million in Year 1, rising to \$3,683,169 million by Year 6 (Table 13). The total cost of the base case (i.e. year 1 to Year 6 total) is \$19,198,014.

The net cost to MBS is the difference in cost calculated by subtracting the proposed listing, MRI and 2D mammogram minus the current listing of 3D mammogram. The type of mammogram will change from 3D alone to 2D with MRI. The difference between the proposed and the current listing in Year 1 is \$2,073,722, rising to \$2,775,108 in Year 6. The total net cost base case is \$14,464,871 over the next 6 years.

Sensitivity analyses were undertaken to explore the assumptions for uptake, rate of growth, ultrasound use, type of mammogram and co-payments. The sensitivity analyses show that six year

cost to the MBS were relatively unaffected by the assumptions except for the use of 3D versus 2D mammograms (Figure 1).

**Figure 1 Five Year Cost to the MBS of including 50 to 59 Patients for breast MRI**



Source: Figure 9, pg 28 of MSAC 1682 Assessment Report

Although the base case assumed that patients aged 50-59 would switch from a 3D mammogram back to an MRI plus a 2D mammogram, it is anticipated that in practice patients would in fact continue to use 3D mammogram. Therefore, it is anticipated that increasing access to MBS item 63464 for high risk patients aged 50 – 59 years will cost approximately \$17,136,091 over six years as presented in Table 3.

**Table 3 Revise net financial implications of MRI in high-risk breast cancer aged 50-59 years**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Number eligible</b>	3,630	3,848	4,079	4,323	4,583	4,858
<b>MRI Breast MBS 63464*</b>	\$2,456,675	\$2,604,076	\$2,760,320	\$2,925,939	\$3,101,496	\$3,287,585

Source: Table 13, pg 28 of MSAC 1682 Assessment Report.

\* using the average benefit paid of \$676.55

## 10. Other relevant information

Nil

## 11. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)