



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1313 – Bone mineral density analyses using Dual Energy X-ray Absorptiometry (DXA) in breast cancer patients receiving aromatase inhibitor treatment

Applicant/s: Australian and New Zealand Bone Mineral Society

Date of MSAC consideration: MSAC 62nd Meeting, 26-28 November 2014

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

An application requesting MBS listing of bone densitometry dual energy X-ray absorptiometry (DXA) for post-menopausal women with early stage breast cancer who receive, or are being considered for, treatment with aromatase inhibitors, was received from the Australian and New Zealand Bone and Mineral Society (ANZBMS) by the Department of Health in June 2011.

2. MSAC's advice to the Minister

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC deferred the application to seek further external evaluation of the economic modelling, especially of the estimates of elevated fracture risks and prescription drug costs.

MSAC also noted that there is currently no corresponding application for PBS listing of any anti-resorptive agent for osteoporosis in the context of patients using an aromatase inhibitor, and requested that PBAC be approached to consider how best to assess this co-dependency.

MSAC separately supported amending the current MBS items for BMD analysis to allow trained technicians to perform DXA scanning under the supervision of a medical practitioner. MSAC considered that this should also involve a fee review of these items.

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

MSAC noted that the application was for MBS listing of bone densitometry dual energy X-ray absorptiometry (DXA) for post-menopausal women with early stage breast cancer who

receive, or are being considered for, treatment with aromatase inhibitors (AIs). Eight studies (two high, four medium, two poor quality) investigating risk of minimal trauma fracture in women taking AIs concluded that women taking AIs for breast cancer have reduced BMD and increased risk of fractures. As summarised by Amir et al, 2011, this evidence suggested a relative risk of 1.5 of fracture reported as an adverse event following an AI compared with tamoxifen, and that 46 patients need to be treated up to five years with an AI for each additional fracture reported.

MSAC noted that this increased risk of fractures was biologically plausible given the mechanism of action of the AIs, which in post-menopausal women act to inhibit aromatase enzyme activity and thereby decrease endogenous oestrogen levels to below levels from natural menopause.

MSAC noted that not requiring the existing highly trained personnel (specialists or consultant physicians) to provide the proposed intervention may lead to improved access, however there was concern about who would identify "appropriately trained" technicians.

MSAC noted that the DXA threshold, beyond which it was proposed, that treatment with anti-resorptive therapy would be initiated was the standard definition of osteoporosis with a T-score below -2.5. This is consistent with the TGA-approved indications of these medicines. However, the frequency of re-testing in patients whose T-score is above -2.5 was more frequent (yearly) than in the proposed clinical management algorithm (one repeat DXA scan after two years and any subsequent DXA scans in limited circumstances).

MSAC noted that the comparator for this intervention was standard clinical assessment involving the use of existing fracture risk assessment tools, vitamin D testing, with lifestyle and dietary advice in the absence of DXA.

MSAC noted that there were no studies that assessed the safety of DXA scans in the population of interest. However, DXA in general, is a widely used technique that is considered to be safe, being non-invasive, and using low levels of radiation, the equivalent of two to four days of background radiation.

MSAC noted the view of ESC that DXA is the reference standard for measuring bone density, but there was limited information on DXA performance in the assessment report. It is reported in a previous assessment (Hailey et al, 1998) to be a high precision method of measuring BMD (the standard basis for diagnosing osteoporosis with respect to a T-score), but its performance in predicting fracture risk is less impressive, whether considered in isolation or combined with other risk factors in an algorithm such as the fracture risk assessment tool (FRAX[®]) developed for online use by the World Health Organisation.

MSAC expressed concern with the standard of the comparative effectiveness data for anti-resorptive therapy included in the assessment report. This was based on 13 medium quality studies and 1 poor quality study (12 randomised trials, one nonrandomised comparative study, and one meta-analysis) investigating treatments to increase BMD for women taking AIs. MSAC agreed with its ESC that the systematic review and meta-analysis conducted for the assessment report contained insufficient, poorly described methods and was difficult to interpret results. In particular, the meta-analyses of mean differences in % change in BMD for lumbar spine and for total hip were reported as standardised mean differences, without reference to the absolute scaling of this change. Hence, the actual BMD change and its clinical meaning are unstated, and this hinders any assessment of the size of the reported benefit on BMD. The economic evaluation presented in the assessment report relied on an

unweighted mean rate ratio for fracture of 0.66 comparing patients on AIs with and without anti-resorptive therapy (or between immediate and delayed anti-resorptive therapy) based on three studies (Brufsky 2012, Llombart, 2012 and Coleman, 2013). Although none of these studies demonstrated a statistically significant reduction of fracture with anti-resorptive therapy, this might be a false negative result due to the studies being under-powered to assess fracture risk.

MSAC also expressed concern that the use of anti-resorptive therapy was associated with harms as well as benefits according to a summary of common adverse events for women taking an AI, which reported increased rates of events such as arthralgia, myalgia, hot flushes and fever for women also receiving BMD management compared with those who did not. The balance of benefits and harms for BMD management was not fully assessed in either the clinical or economic evaluation.

A cost-utility analysis was undertaken on the basis that the evidence showed that DXA together with the use of anti-resorptive therapy in women assessed to have osteoporosis was superior to standard clinical assessment for reversing bone loss and reducing fracture in women taking AIs. MSAC expressed concerns about the economic model, the assumptions made and the validity of the modelled estimates of cost-effectiveness, noting that:

- The relative risk of fracture due to osteoporosis compared with no osteoporosis was estimated by extrapolating the relative risk of fracture per standard deviation decrease in BMD estimated in the systematic review by Marshall et al (1996). The base case relative risk was 3.75 (with a narrow range of 3.50 - 4.00 used for the sensitivity analysis), which MSAC noted to be greater than the observed relative risk of 1.5 for fracture due to receiving AI compared to not receiving AI;
- It was assumed all minimal trauma fractures would result in hospitalisation with an annual cost of \$11,974 (likely to be an overestimate);
- The model estimated increases in overall survival for women taking anti-resorptive agents compared to those who did not.
- A minor problem included the assumption that zoledronic acid was administered twice a year.

Overall, MSAC considered that the resulting incremental cost-effectiveness ratio was likely underestimated. MSAC noted that PBS subsidy of anti-resorptives has been limited to patients at risk of fracture greater than that predicted by having osteoporosis defined solely by a T-score less than -2.5, which suggests a need to calibrate the model results from the assessment report with models accepts as the basis of PBAC decision-making. However, MSAC also noted that with recent price reductions for PBS-listed anti-resorptive therapy, some are now below the co-payment for general beneficiaries. MSAC sought advice on whether an anti-resorptive therapy sponsor could be found to confirm pricing and supply of its product for use in patients who both take AIs and have osteoporosis as defined by a T-score less than -2.5, or whether a case could be made that PBS subsidy would not be important for most of this eligible population given current pricing. Either way, the case of DXA testing of patients who take AIs does not need to be remade for MSAC beyond demonstrating a linked clinical utility argument to cost-effective anti-resorptive management of those shown to also have osteoporosis.

MSAC noted that the costs to the MBS over 5 years were estimated to be \$13.372 million for annual DXA scans and \$10.203 million for two yearly scans.

MSAC noted errors in the financial analysis including:

- Frequency of the DXA scans;

- Omission of the costs to the MBS for 2 general practitioner (GP) visits;
- Co-payment for risedronate was ignored;
- Eligibility for DXA scans via existing MBS items and for anti-resorptive therapies as currently listed on the PBS;
- Overestimation of assumed compliance to risedronate; and
- The effects of the safety net were not considered.

4. Background

MSAC has not previously considered BMD measurement using DXA in breast cancer patients receiving aromatase inhibitor treatment.

DXA scanning is not currently funded for men and women below the age of 70 unless they suffer from certain pre-defined conditions. DXA scanning under the schedule is currently available to persons aged 70 and over (MBS item number 12323), for people who have previously experienced a minimal trauma fracture and for those with one of several risk factors for osteoporosis including: prolonged corticosteroid use, hypogonadism, primary hyperparathyroidism, chronic liver disease, chronic renal disease, proven malabsorptive disorders, rheumatoid arthritis, or conditions associated with thyroxine excess (MBS items 12306 to 12321).

Quantitative computed tomography (QCT) is also listed on the MBS for measuring BMD, for mostly the same indications.

5. Prerequisites to implementation of any funding advice

DXA scanners are already approved for use in Australia through the TGA.

Four DXA scanning machines are currently used in Australia. Operators and technicians of DXA scanners are required to have accreditation in Australia. The ANZBMS run courses which, upon completion, award participants with a Certificate of Completion in Clinical Bone Densitometry. This satisfies the requirements of radiation safety legislation in most Australian states.

6. Proposal for public funding

DXA scanning is proposed by the application for post-menopausal women with early stage breast cancer who are being considered for, or are being treated with, aromatase inhibitors and who are not otherwise eligible for a DXA scan with no age restriction.

The application's proposed MBS item, consistent with that specified in the DAP, is shown below.

Bone densitometry (performed by a specialist or consultant physician where the patient is referred by another medical practitioner), using **dual energy X-ray absorptiometry**, for the measurement of bone mineral density in **patients with breast cancer who are currently being treated with or are about to commence treatment with aromatase inhibitors**.

Measurement of 2 or more sites – **1 service only in a period of 12 consecutive months** - including interpretation and report; not being a service associated with a service to which item 12306, 12309, 12312, 12315, 12318, 12321 or 12323 applies

Fee: \$102.40 **Benefit:** 75% = \$76.80 85% = \$87.05

[Relevant explanatory notes]

D1.27, Bone Densitometry – (Items 12306 to 12323)

The proposed item would be in addition to existing MBS items for DXA.

Currently, no specific PBS-listed medicine is proposed for use in this population.

For patients with BMD T-scores ≤ -2.5 , repeat scans are already available through the existing MBS item 12306. At age 70 or greater, a patient is eligible for MBS item 12323. If a patient has undergone premature menopause as a consequence of breast cancer chemotherapy treatment and is under age 45, she is eligible for MBS item 12312.

Bone density scanning can be performed at any location which has both a DXA machine and qualified technician. A radiologist, nuclear medicine physician or other accredited specialist is required to perform the test and interpret the results. Communication of the results to the patient is facilitated through the patient's referring practitioner.

7. Summary of Public Consultation Feedback/Consumer Issues

Public consultation submissions received were strongly supportive of the proposed intervention.

The Breast Cancer Network Australia reported survey results that suggest 30% of women taking aromatase inhibitors had a DXA scan every 12 months, and almost 30% every two years. Some women reported having up to six DXA scans in conjunction with their aromatase inhibitor treatment, fully paid by the patient.

Public feedback also noted that there should be no age restriction detailed in the listing and that the listed indication should be for women being considered for hormonal treatment of breast cancer.

Consumer representatives noted that the proposed treatment regimen may be disruptive and require travel and accommodation costs for consumers, with associated productivity, out of pocket and other financial costs.

Consumer representatives also noted that the SBA does not demonstrate cost benefit from a consumer perspective and that the long term impact/benefit was not identified in the assessment report.

Consumer representatives questioned whether consumers would require repeat treatments of the proposed intervention and how early identification of osteoporosis would have a subsequent effect on one's quality of life. Consumer representatives noted that these data were missing from the assessment report.

Consumer representatives also noted that a person may need to balance the side effects of the proposed intervention with other tests and interventions and that, in some cases, a lifestyle intervention could be preferred.

Consumer representatives noted that the DXA scan was easy to use and supported by some clinical and consumer groups, in particular the Breast Cancer Network of Australia – a strong consumer advocacy voice.

8. Proposed intervention's place in clinical management

In hormone receptor-positive breast cancer, the proliferation of mammary carcinoma cells is dependent on oestrogen. Common therapies for hormone receptor positive post-menopausal breast cancer include aromatase inhibitors and tamoxifen. The aromatase inhibitors have a negative impact on bone density due to the inhibition of overall oestrogen production within the body.

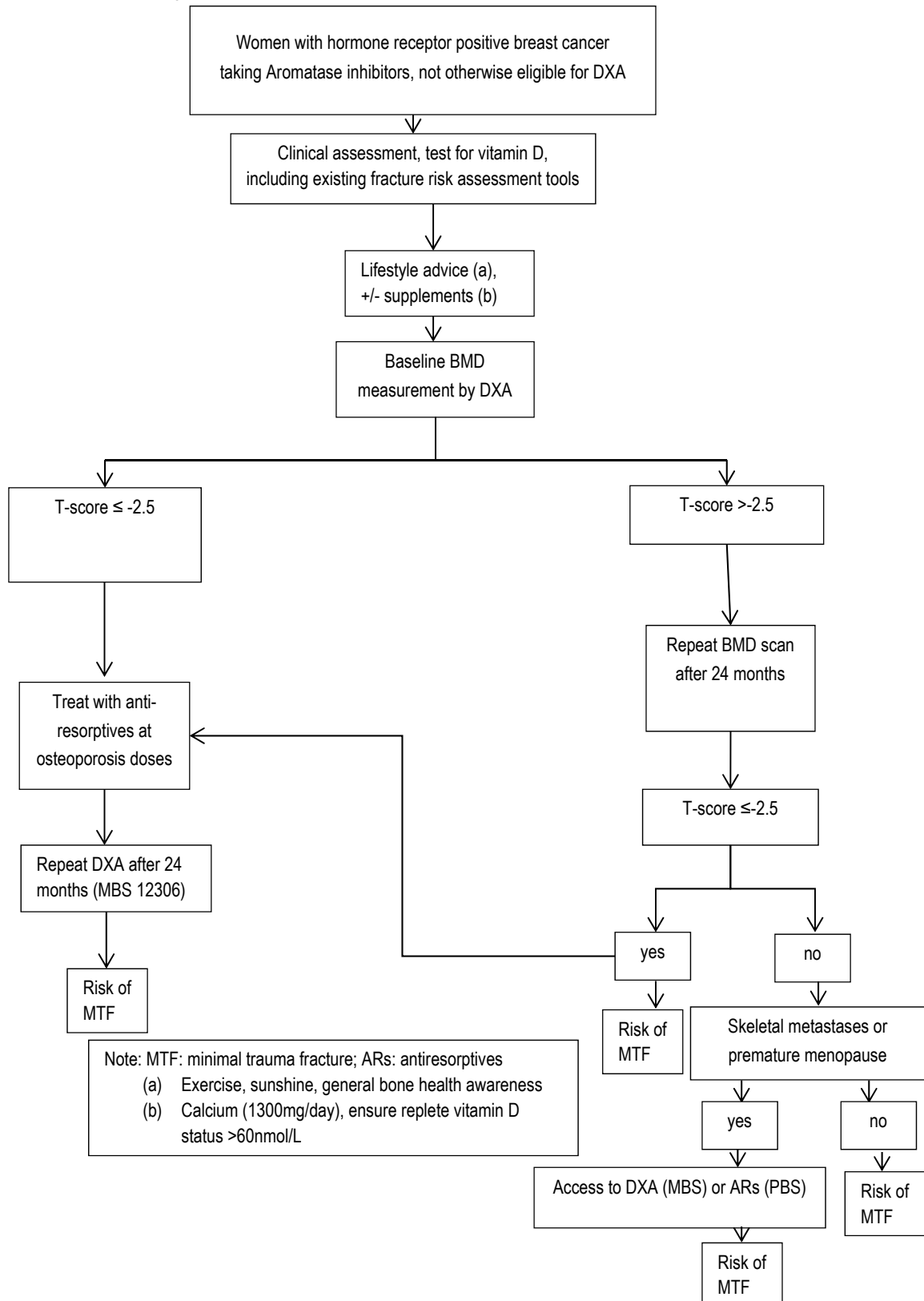
DXA is a diagnostic procedure introduced into routine clinical practice as a method to measure bone mineral density (BMD). Clinicians use DXA to diagnose osteopenia and osteoporosis and appropriately treat individuals to prevent fractures. The DXA scan is used to generate a T-score, a comparison of a patient's bone density to that of peak bone density for the patient's gender and is the number of standard deviations above or below the normal young adult BMD gender-specific mean. BMD is often measured at the lumbar spine (L2-L4), total hip and femoral neck.

Figure 1 shows the clinical management algorithm for the proposed new intervention which indicates that patients on aromatase inhibitors (AIs) would be assessed at baseline for osteoporosis.

If a patient has osteoporosis as determined by a BMD T-score ≤ -2.5 , she would start anti-resorptive therapy, or otherwise be re-tested after 2 years. If at this time the patient has osteoporosis, they would start anti-resorptive therapy or if not, would only receive a third DXA and/or anti-resorptive therapy if she develop skeletal metastases or premature menopause. The clinical evidence addressed the requirements of the agreed Protocol.

The applicant stated in its preMSAC response that the algorithm below does not reflect the expert opinion of the society in regards to clinical testing for vitamin D, the effects of AI therapy on the skeleton and development of skeletal metastases. The applicant also noted that there appears to be no consensus on the frequency of BMD monitoring in AI treated patients. However, the management plan as per figure 1 is appropriate in an Australian setting.

- Figure 1: Proposed clinical management algorithm of breast cancer patients receiving aromatase inhibitor therapy



(Adapted from information provided by the applicant and Reid DM, Doughty J, Eastell R, Heys SD, Howell A, McCloskey EV, Powles T, Selby P, Coleman RE. Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK Expert Group. Cancer Treat Rev 2008;34:S1–S18)

9. Comparator

Clinical assessment including use of existing fracture risk assessment tools, vitamin D testing, with lifestyle and dietary advice. MSAC considered this was appropriate.

The applicant in its preMSAC response did not consider this was an appropriate alternative to DXA measurement.

10. Comparative safety

No studies assessed safety of DXA scans in the population of interest. But in general:

- DXA is regarded as non-invasive and safe and is widely used;
- A review and an observational study found that DXA is associated with negligible amounts of radiation that are below background levels;
- No issues were reported on radiation safety in the studies reviewed; and
- “A patient undergoing DXA scans for a lifetime has a negligible increased risk of developing cancer” (Bandirali 2013).

Information was provided in the assessment on the safety of anti-resorptive therapies.

11. Comparative effectiveness

Primary Source(s) of Evidence

- 8 studies (2 high, 4 medium, 2 poor quality) on risk of minimal trauma fracture (MTF) in women taking AIs. The Protocol stated that the change in BMD measured by DXA is an appropriate surrogate marker for risk.
- 7 studies (medium-high quality in large populations with large person-years of observation across many countries - 3 meta-analyses, 2 HTA reports, 1 review, 1 case-control study) on effectiveness and safety of DXA scans.
- 14 studies (13 medium, 1 poor quality - 12 RCTs, 1 comparative study, 1 meta-analysis) on treatments to increase BMD (most common was zoledronic acid) for women taking AIs.
- 3 studies (all high quality) on cost-effectiveness of DXA and BMD interventions for women taking AIs.

Main Results

Fracture risk for women using AIs

Number needed to harm: 46 women treated with AIs resulted in 1 fracture (Amir et al 2011, high quality systematic review)

- ~1.5-fold increased risk of MTF due to AIs (Becker et al 2012, high quality systematic review).
- No studies compared risk of fracture in women with breast cancer taking AIs with other high risk populations such as those on long-term corticosteroid therapies.
- Retrospective analysis of large population-based cohort of women with breast cancer reported higher risk of fracture if treated with AIs compared with tamoxifen or no hormone therapy (Neuner et al 2011, medium quality).
- In 7-year follow-up of ATAC trial (Eastell et al 2011, medium quality) bone loss was accelerated during use of AIs, was partially restored after treatment cessation, but did not return to baseline levels.

Comparative effectiveness – DXA

Evidence was available for post-menopausal women, but not specifically for the population of interest. BMD measurement has low sensitivity but high specificity for hip fractures and is not recommended for screening in the general population (Marshall et al 1996, medium quality systematic review). A meta-analysis concluded that combined use of clinical risk factor assessment and BMD is optimal as it provides the most effective prediction of fracture risk and need for anti-resorptive therapies (Kanis et al 2007, medium quality). A health technology assessment report (Hailey et al 1998, strong evidence) concluded that DXA has the best test performance compared with other BMD technologies: 3-6% coefficient of variation and 1-3% precision.

Comparative effectiveness – treatments for low BMD

Consistent evidence was presented in the assessment that anti-resorptive therapies significantly improved BMD in women taking AIs regardless of prior treatment with chemotherapy or tamoxifen.

12. Economic evaluation

A cost-utility analysis was presented on the basis that the evidence showed that DXA together with the use of anti-resorptive therapy was superior for reversing bone loss in women taking AIs. Three high quality (based on the CHEERS criteria) published economic studies were identified, but none were Australian. One was considered applicable to the proposed clinical setting (Ito et al 2012) and the Markov modelling methods used informed the development of an economic model for the Assessment Report.

Issues raised about the model, included the assumptions made and the validity of the modelled estimates of cost-effectiveness. For example:

- The relative risk (RR) of fracture due to osteoporosis (T-score \leq -2.5) was estimated by extrapolating the relative risk of fracture per standard deviation decrease in BMD estimated in the systematic review by Marshall et al (1996). The base case used RR=3.75, with a narrow range (3.50-4.00) for the sensitivity analysis.
- It was assumed that all minimal trauma fractures would result in hospitalisation and furthermore that the annual cost of treating a vertebral fracture was \$11,974 (likely to be a considerable overestimate).
- The key model parameter, RR of fracture in women on AIs taking anti-resorptive therapy compared with those not taking anti-resorptive therapy was estimated to be 0.66 based on pooled proportions of women who had fractures with and without anti-resorptive therapy from different studies.

Other minor problems included the assumption that zoledronic acid was administered twice a year, not once.

13. Financial/budgetary impacts

An epidemiological approach was used to assess the financial implications of listing DXA for women with breast cancer taking AI therapy.

The base case used in the analysis assumed the anti-resorptive therapy risedronate would be used, with the costs of zoledronic acid (again incorrectly assumed to be administered twice a year) considered in sensitivity analysis.

There were some errors in the analysis:

- It was assumed that DXA scans would be provided annually for all women over the five year horizon while the proposed clinical management algorithm indicated that those with T-scores >-2.5 would have a baseline scan and then a repeat scan after two years and then subsequent DXA scans only for those who develop skeletal metastases or premature menopause at which time they would be eligible for DXA scans and AR therapy under existing MBS and PBS items.
- Costs to the MBS for two GP visits per year associated with risedronate therapy were omitted.
- The considerable copayment for general patients for risedronate was ignored (PBS maximum dispensed price is \$45.60 per month with a copayment of \$36.90 for general patients, or \$6.00 for concession patients).
- Consideration was not given for women in the population of interest becoming eligible for DXA scans via existing MBS items and for anti-resorptive therapies as currently listed on the PBS.
- Assumed compliance to risedronate was high (100% in year 1 to 80% in year 5). This may be overestimated, with potential compliance to zoledronic acid (once per year) or denosumab (twice per year) being higher with higher costs to the PBS.
- Effects of the safety net were not considered.

Costs to the MBS over 5 years were estimated to be \$13.4 million for annual DXA scans and \$10.2 million for two yearly scans.

The total costs to the health system (MBS+PBS less savings to the States for fractures avoided) would be \$19.1 million for annual DXA scans. MSAC noted the ESC suggestion that it is not likely that freed resources from fractures averted would be realised as financial savings.

In sensitivity analyses the costs to the MBS are relatively stable with the differences in costs to the PBS impacting on the total costs.

Table 30: Results of the financial estimates over next five years

	2015	2016	2017	2018	2019
Eligible population	-	-	-	-	-
Incidence of women with brca aged 50-69	8,108	8,293	8,479	8,665	8,851
Proportion with early stage	7297	7464	7631	7798	7966
Proportion taking aromatase inhibitors	5911	6046	6181	6317	6452
Total number of women each year	5911	11956	18138	24454	30906
Estimated uptake of DXA scans	-	-	-	-	-
Number of scans if annual	5911	11956	18138	24454	30906
Estimated women taking anti-resorptives	-	-	-	-	-
Proportion of women with osteoporosis	866	1752	2657	3583	4528
Total women treated	866	1752	2657	3583	4528
MBS Costs	-	-	-	-	-
DXA scans x uptake	\$514,510	\$1,040,770	\$1,578,913	\$2,128,721	\$2,690,367
Vitamin D tests	\$167,444	\$338,723	\$513,838	\$ 692,788	\$875,574
GP visits	\$183,120	\$370,434	\$561,943	\$757,647	\$957,546
PBS Costs of anti-resorptives	-	-	-	-	-
Annual cost of risedronate	\$473,815	\$958,484	\$1,454,006	\$1,960,382	\$2,477,611
Compliance rate of anti-resorptive	100%	95%	90%	85%	80%
Total cost of anti-resorptives	\$473,815	\$910,560	\$1,308,605	\$1,666,324	\$1,982,089
Hospital cost savings from fracture prevention	-	-	-	-	-
Expected incidence of fractures (all women on AI)	85	172	261	352	445
Number of women untreated	5045	10205	15481	20872	26379
Number of fractures in untreated women	73	147	223	301	380
Number of fractures in treated women	8	17	25	34	43
Fractures prevented	4	9	13	18	22
Cost of fractures avoided (weighted mean AR-DRG)	\$9,065	\$ 9,065	\$9,065	\$9,065	\$9,065
Total cost savings	-\$38,453	-\$77,787	-\$118,002	-\$159,098	-\$201,074
TOTAL MBS COSTS	\$865,074	\$1,749,927	\$2,654,694	\$3,579,156	\$4,523,487
TOTAL PBS COSTS	\$473,815	\$910,560	\$1,308,605	\$1,666,324	\$1,982,089
TOTAL STATE GOVT COST SAVINGS	-\$38,453	-\$77,787	-\$118,002	-\$159,098	-\$201,074
TOTAL COSTS	\$1,300,436	\$2,582,699	\$3,845,297	\$5,086,383	\$6,304,502

AI = aromatase inhibitor, AR-DRG = Australian Related Diagnosis Relative Group, brca = breast cancer, DXA = dual x-ray absorptiometry, MBS = Medical Benefits Schedule , PBS= Pharmaceutical Benefits Schedule.

14. Key issues from ESC for MSAC

ESC noted that the target population was post-menopausal women with early stage breast cancer who receive or are being considered for treatment with aromatase inhibitor (AI) therapy. AI therapy is associated with rapid bone loss which elevates the risk of minimal trauma fracture. ESC further noted that the population of interest is post-menopausal women under the age of 70, as existing items on the MBS are available from age 70.

ESC expressed concern that this application had been submitted to the Medical Services Advisory Committee (MSAC) without a co-dependent application to PBAC for the anti-resorptive therapy. The application depends on these prescription medicines which are not

currently subsidised on the Pharmaceutical Benefit Schedule (PBS) for the proposed population. There is no application before PBAC to expand eligibility to this group.

As such, ESC was concerned that the model to be considered by MSAC should be calibrated against models already assessed by PBAC. This would have been achieved readily through an integrated co-dependent application to both MSAC and PBAC. Such an application would need the support of at least one supplier of a suitable anti-resorptive to confirm pricing and supply for consideration through the PBS.

ESC felt that it could not comment on those aspects of the application dealing with the safety or effectiveness of anti-resorptive therapies for the target population. ESC considered, however, that there was little benefit in testing the population of interest if treatment options were limited to lifestyle advice, calcium and vitamin D supplements.

Because of the co-dependence between DXA scanning and use of anti-resorptive therapies ESC concluded that it was unable to provide a full appraisal of the economic evaluation. However, ESC was concerned about the quality and validity of the economic model. There were concerns about estimates used for some of the key parameters, costs of vertebral fractures and other errors identified.

ESC also noted a discrepancy between the frequency of DXA scan use stated in the proposed item descriptor (12 months) and included in the base case for the economic evaluation and financial implications and the frequency stated in the proposed clinical algorithm (2 years).

ESC noted that currently, all BMD items listed on the MBS require the test to be personally performed by a specialist or consult physician. ESC noted that, in practice, technicians are appropriately skilled and more likely to provide the service, and that this may necessitate adjustment of the proposed fee.

15. Other significant factors

Nil.

16. Applicant's comments on MSAC's Public Summary Document

The applicant states that there is a clear clinical need for monitoring skeletal health in patients prescribed aromatase inhibitors (AIs). The evidence indicates that bone loss and fracture can be prevented by anti-fracture therapy in this population. Furthermore, there is an equity issue wherein men prescribed Androgen Deprivation Therapy (ADT) have similar skeletal comorbidities and can access bone densitometry under the male hypogonadism indication whereas women using AIs are eligible for subsidised scans only if they are under 45 years of age, are over 70 years of age or have already suffered a fragility fracture. There is clearly a demand for access to bone densitometry as indicated in the consumer comments wherein 30% of women prescribed are have annual DXA scans and 30% are having examinations every two years and the consumer response is broadly supportive of the application. Based on observations that bone loss is rapid, particularly in the first year, it is ANZBMS' recommendation that bone density assessments should ideally be undertaken before or as soon as possible after initiation of therapy and 12 months after commencement of therapy (this could potentially be limited to women with osteopenia on their baseline scan). Subsequent examinations might then be undertaken using existing item numbers – monitoring of low bone mass (Item 12306) or significant change in drug therapy (Item

12321). ANZBMS has consistently criticized the MSAC algorithm and agree that the economic evaluation is flawed with some overestimation of both costs and benefits.

The issue regarding PBS indications for therapy is a separate though related issue and treatment decisions will be made by patients and clinicians taking into account the risks and benefits as well as cost (where there is no current PBS indication) as we do for other clinical scenarios where patients are not eligible for PBS-subsidised medication. Similarly, the issue about who performs densitometry and how it is remunerated is a separate issue that will need to be addressed independent of this application.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.