



Australian Government

Medical Services Advisory Committee

## Public Summary Document

### *Application 1162 – Bone Mineral Density analyses using dual energy X-ray absorptiometry (DXA) for women in their 50<sup>th</sup> year*

**Sponsor/Applicant/s:** Professor Christopher Nordin and Professor Richard Prince

**Date of MSAC consideration:** MSAC 62<sup>nd</sup> 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](http://www.msac.gov.au).

#### **1. Purpose of application and links to other applications**

An application requesting MBS listing of dual energy X-ray absorptiometry (DXA) for women in their 50<sup>th</sup> year was received by the Department of Health in June 2011.

The application proposed provision of an MBS item number for femoral neck and lumbar spine bone densitometry by DXA for all women in their 50<sup>th</sup> year with a view to, at an early stage, identifying individuals with a low or low-normal bone mineral density (BMD) (that is individuals with a negative T-score) who may be at future increased fracture risk and who would be given appropriate dietary and lifestyle advice for maintaining bone density.

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

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC does not support public funding DXA screening for women aged 50 years. This was based on the following:

- There was no demonstrated advantage of DXA over other methods of fracture risk assessment such as the FRAX<sup>®</sup> online assessment tool; and
- Currently Medicare benefits are not payable in respect of a health screening service.

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

MSAC noted that the application was for provision of an MBS item number for femoral neck and lumbar spine bone densitometry by DXA for all peri-menopausal women in their 50<sup>th</sup> year in order to identify those with a low bone mineral density (BMD) at increased fracture risk and who would be given appropriate dietary and lifestyle advice. MSAC understood that

this population was proposed because it is known to be associated with an accelerated rate of bone loss.

MSAC considered that, at the time of testing, this target population would not have a combination of risk factors (eg being female and peri-menopausal) that would sufficiently differentiate the requested testing arrangements from a primary health screening service given that they are otherwise healthy. In this regard, MSAC noted that Section 19 (5) of the *Health Insurance Act 1973* generally prevents payment of Medicare benefits for screening services stating:

"Unless the Minister otherwise directs, a Medicare benefit is not payable in respect of a health screening service, that is to say, a professional service that is a medical examination or test that is a medical examination or test that is not reasonably required for the management of the medical condition of the patient." As the proposed item is essentially a screening test MSAC requested clarification about whether funding of this item was outside the remit of the MBS.

MSAC noted that the comparator to the proposed DXA item is clinical risk assessment without DXA using, for example, the fracture risk assessment tool (FRAX<sup>®</sup>) developed for online use by the World Health Organisation, but without inputting BMD data.

MSAC considered that DXA is safe, being non-invasive, and using low levels of radiation, the equivalent of two to four days of background radiation.

However, MSAC noted that there were no studies that assessed DXA screening and fracture rates over the long-term and that screening of BMD is not recommended in any international guideline. Therefore, the effectiveness of DXA screening in improving health outcomes was assessed based on three questions:

- How accurate is adding a DXA-based BMD result to generate a FRAX<sup>®</sup> score compared to generating a FRAX<sup>®</sup> score without inputting a BMD result?
- Does generating a DXA result influence lifestyle changes?
- Do these lifestyle changes improve health outcomes?

In terms of accuracy, MSAC noted that, from the studies presented (Cheung et al, 2012; Tamaki et al, 2011), BMD alone versus FRAX<sup>®</sup> without BMD versus FRAX<sup>®</sup> with BMD all had similar area under the receiver operating characteristic curve (AUROC) values and thus, the addition of BMD to FRAX<sup>®</sup> does not increase the predictive ability of the FRAX<sup>®</sup> model, particularly for individuals otherwise at low risk of fracture. These values were modest, varying between 0.64 and 0.73 for major osteoporotic fracture and between 0.82 and 0.90 for hip fracture. The studies were conducted in mainly older women (mean age of 62 years in Cheung et al, 2012 and 57 years in Tamaki et al, 2011), so would be more likely to detect an incremental predictive effect of adding BMD results than the target population of women in their 50th year. MSAC also considered that, although these studies were conducted in mainly Asian populations, their results in relative terms could be regarded as sufficiently applicable to the Australian context.

In terms of influencing lifestyle changes, MSAC noted that the addition of DXA screening results to questionnaires compared in a randomised trial (Sedluk et al, 2007 in 203 postmenopausal women) to a control group receiving questionnaires alone resulted in greater increases over the following year in women taking calcium and osteoporosis medications, but with no change in alcohol, smoking or exercise. Of these results, MSAC considered that the

net clinical benefit to patients of increasing calcium intake remains unclear due to elevated cardiovascular risks, and the failure to improve exercise may be important because increasing exercise may particularly contribute to reducing fracture risk by reducing the risk of falling.

In terms of improved health outcomes, MSAC noted that there was no basis to estimate the extent of any improved health outcomes from any reported extent of lifestyle change.

MSAC noted that no economic evaluation was presented as there was no demonstrated advantage of DXA over other methods of risk assessment. The proposed fee was the same as all other DXA-BMD items already on the MBS, however, no justification was provided for these costs.

The expected volume of use is 40% of Australian females aged 50 years and the expected frequency of use is once per patient over their lifetime. MSAC noted that the budgetary impact depended on the uptake of the service, with 10% uptake translating to a total MBS impact of approximately \$2 million in the first year and an 80% uptake translating to approximately \$16 million.

#### **4. Background**

MSAC has not previously considered BMD measurement using DXA for women in their 50<sup>th</sup> year.

Unconditional access to DXA scanning is currently available to persons aged 70 years and over (MBS item 12323). Conditional access to DXA scanning is also currently available if a person meets certain criteria (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.

Operators and technicians of DXA scanners are required to have accreditation in Australia. The Australian and New Zealand Bone and Mineral Society (ANZBMS) runs 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

The application's proposed MBS item is shown below:

Category 2 – DIAGNOSTIC PROCEDURES AND INVESTIGATIONS, Bone Densitometry

### **MBS XXXX**

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 hip and spine bone mineral density in women in their 50<sup>th</sup> (or 55<sup>th</sup> or 60<sup>th</sup>) year.

Measurement of 2 or more sites –1 service only – including interpretation and report; not being a service associated with a service to which item 12306, 12309, 12312, 12315, 12318, 12321 or 12323 applies (Ministerial Determination).

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

Other relevant notes from D1.27, Bone Densitometry – (Items 12306 to 12323)

As DXA scanning is already on the MBS for other indications, the proposed fee is the same as the existing MBS item numbers.

DXA scanning is proposed for the target population of women in their 50<sup>th</sup> year who are not eligible for a DXA scan through existing MBS items. The choice of the 50<sup>th</sup> year was proposed since this approximates to the average age of menopause in Australia.

Women diagnosed with osteoporosis (T-score  $\leq -2.5$ ) would be eligible for repeat testing as required under MBS item 12306.

DXA scanning can be performed at any location which has a DXA machine and a qualified technician. The scans should be critically assessed by the densitometrist and interpreting physician for abnormalities that can affect BMD measurements (El Maghraoui & Roux 2008).

## 7. Summary of Public Consultation Feedback/Consumer Issues

Consumers noted that, not requiring highly trained personnel to provide the proposed intervention may lead to improved access. However, they were concerned about who would identify 'appropriately trained' individuals.

Consumers were also concerned that no long term impact or benefit regarding the proposed indication was provided and that consumer impact in general was not addressed in the assessment report. For example, travel costs and lack of productivity which consumers may incur were not addressed.

Consumers also questioned whether consumers would have repeat or combined scans.

## 8. Proposed intervention's place in clinical management

Osteoporosis is a condition in which the bones become fragile and brittle, leading to a higher risk of fractures (breaks or cracks) than in normal bone. Fractures due to osteoporosis (osteoporotic fractures) can lead to changes in muscle weakness, loss of height and bone deformity of the spine. Fractures can lead to chronic pain, disability, loss of independence and even premature death.

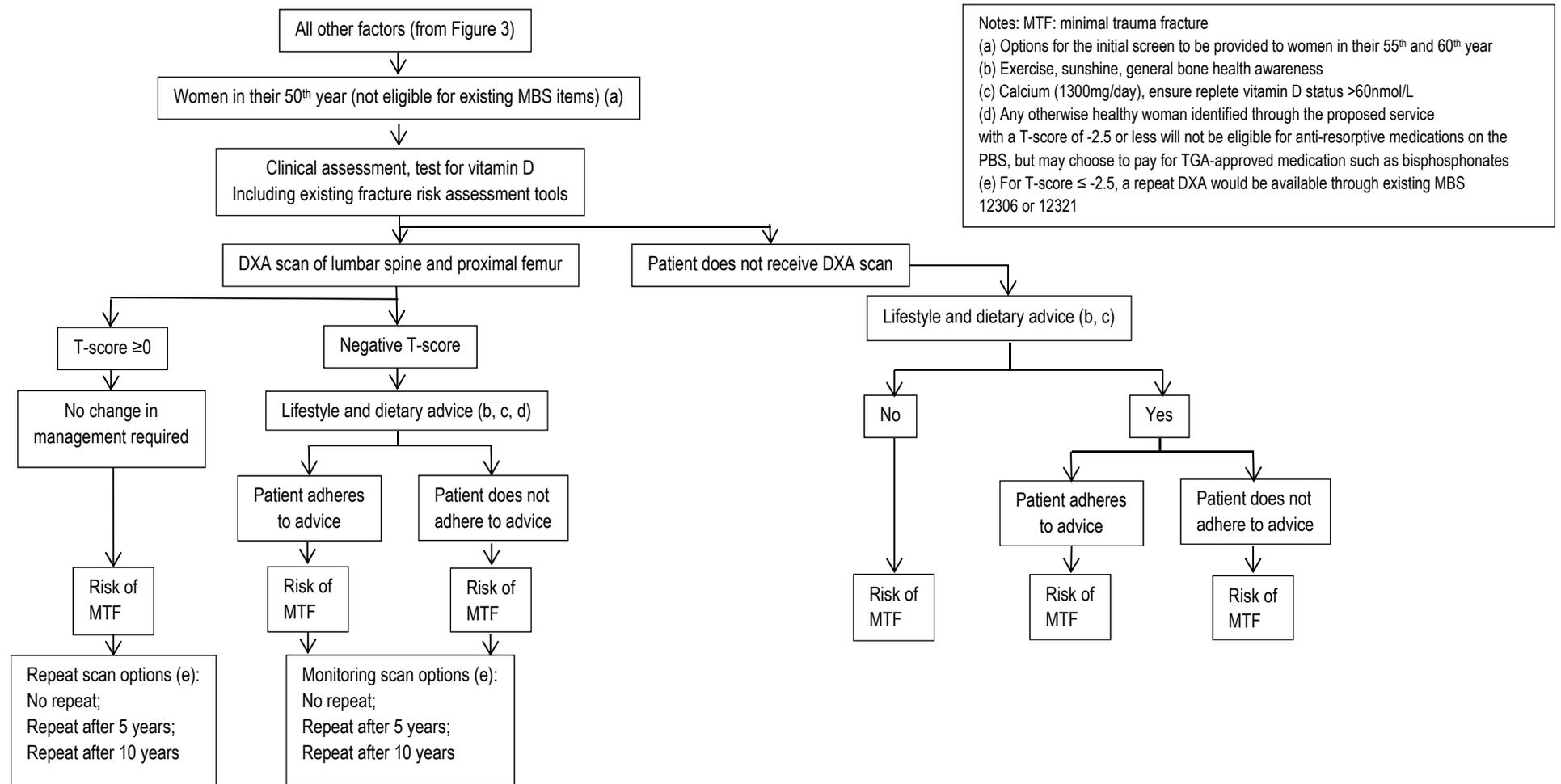
The prevalence of osteoporosis is high in women due to a decrease in oestrogen levels after menopause which results in higher levels of bone loss per year than in men.

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 gender-specific BMD mean. BMD is often measured at the lumbar spine (L2-L4), total hip and femoral neck.

DXA would be used in combination with lifestyle and dietary advice to encourage women in their 50<sup>th</sup> year with a BMD that is lower than the mean (T-score < 0) to change their lifestyle to prevent future osteoporosis and minimal trauma fractures. As postmenopausal osteoporosis is both predictable and preventable, a change in lifestyle and diet at age 50 in those who are at risk of developing osteoporosis could significantly reduce the fracture burden.

The proposed item number would be used in addition to the existing MBS items for DXA and QCT.

The figure shows the clinical management algorithm for the proposed new intervention:



## 9. Comparator

The comparator to the proposed DXA item was clinical risk assessment without DXA, including use of risk assessment (eg, the FRAX (WHO) online tool). Evidence was searched for all methods of risk assessment, however evidence was only found for the FRAX tool.

## 10. Comparative safety

There are no studies that specifically investigate the safety of DXA testing as the ionising radiation dose is so low.

## 11. Comparative effectiveness

There is no study looking at DXA screening and fractures rates over the long-term. It was also noted that screening of BMD is not recommended in ANY international guideline.

Gutin et al (1992) and Winzenberg et al (2006) were used to investigate the effectiveness of DXA screening on BMD as a surrogate of fracture risk; neither of these had a control group and both relied on expected patterns from previous studies as the control. Gutin et al (1992) found no difference in BMD at hip or spine, compared to expected decline in BMD. Winzenberg et al (2006) found no difference between leaflet and course but there was increase in BMD of 1.1% per year at hip not spine (combined), compared to expected stability.

Cheung et al (2012) and Tamaki et al (2011) were used to investigate the effectiveness of fracture risk assessment using FRAX alone versus FRAX and BMD (via DXA) combined. Tamaki et al (2011) found BMD alone versus FRAX had a very similar area under the curve (AUC)AUROC, i.e. ~ between 0.7-0.9 and that adding BMD to FRAX did not increase the AUROC significantly.

Sedlak et al (2007), Winzenberg et al (2006) and Gutin et al (1992) were used to investigate the effectiveness of DXA testing to influence lifestyle changes in the study participants. The main results from these studies were that:

- BMD measurement alone vs FRAX has a very similar predictive accuracy as assessed by the area under the ROC curve (AUC). Adding BMD to FRAX does NOT increase the predictive ability of the model.
- Low quality data from 2 studies indicating stability in BMD at hip or spine with DXA, compared to expected decline in BMD without DXA, based on historical controls.
- No difference between DXA and leaflet vs DXA and course but increase in BMD of 1.1%/year at hip (not spine) (in combined groups), compared to expected stability without DXA; again based on historical controls.
- Both groups had increased calcium use over time but increase was higher in intervention group ( $p < 0.001$ ).
- Greater increase in women taking osteoporosis medications in intervention groups compared to control (19% vs 6%).
- No between group difference in changes in alcohol or smoking or exercise.
- Low BMD group increased calcium supplements more than high BMD group.
- These studies were not directly compared to FRAX or another clinical tool and were all biased by large loss to follow-up, which would tend to include those patients interested in their health and overestimate protective effects

## **12. Economic evaluation**

No economic evaluation was presented as there is no demonstrated advantage of DXA over other methods of risk assessment.

## **13. Financial/budgetary impacts**

The expected volume of use is 40% of Australian females aged 50 and the expected frequency of use is once per patient over their lifetime.

The proposed fee of \$102.40 is the same as all other DXA BMD items already on the MBS. However, no justification has been provided for the costs. Estimated patient out-of-pocket costs are \$40 to \$50 per service.

The total cost of the intervention was estimated to be around \$8.6 million over 5 years.

## **14. Key issues from ESC for MSAC**

ESC noted that the proposed population, asymptomatic women in their 50<sup>th</sup> year, meant that the proposal was for a screening service. ESC noted that Section 19 (5) of the *Health Insurance Act 1973* generally prevents payment of Medicare benefits for screening services, stating:

" Unless the Minister otherwise directs, a Medicare benefit is not payable in respect of a health screening service, that is to say, a professional service that is a medical examination or test that is not reasonably required for the management of the medical condition of the patient."

ESC acknowledged that the prevalence of osteoporosis (approximately 4%) was presented but noted that data regarding fracture prevalence was absent. ESC concluded that the absence of data on prevalence cast considerable doubt on the effectiveness of the test's ability to prevent fractures in later life.

ESC also noted that DXA is the reference standard for diagnosing osteoporosis. However, ESC was concerned that none of the studies presented followed through to capture the outcome of fracture later in life. ESC considered that prediction of future fractures for women in their 50<sup>th</sup> year would be poor, as peak bone loss occurs after this age.

ESC noted that, worldwide, there is no guideline which recommends DXA screening.

## **15. Other significant factors**

Nil

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

The applicant had no comment.

## **17. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website at: [www.msac.gov.au](http://www.msac.gov.au).