
**Medicare Benefits Schedule Review
Taskforce**

**Second report from the
Diagnostic Imaging Clinical
Committee - Bone Densitometry**

August 2016

Important note

The views and recommendations in this review report from the clinical committee have been released for the purpose of seeking the views of stakeholders.

This report does not constitute the final position on these items which is subject to:

△ Stakeholder feedback;

Then

△ Consideration by the MBS review taskforce;

Then *if endorsed*

△ Consideration by the minister for health; and

△ Government.

Stakeholders should provide comment on the recommendations via the [online consultation tool](#).

Confidentiality of comments:

If you want your feedback to remain confidential please mark it as such. It is important to be aware that confidential feedback may still be subject to access under freedom of information law.

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1. Executive Summary

The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 5,700 items on the MBS can be aligned with contemporary clinical evidence and practice and improves health outcomes for patients. The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key goals:

- △ Affordable and universal access
- △ Best practice health services
- △ Value for the individual patient
- △ Value for the health system

The Taskforce has endorsed a methodology whereby the necessary clinical review of MBS items is undertaken by Clinical Committees and Working Groups. The Taskforce has asked the Clinical Committees to undertake the following tasks:

1. Consider whether there are MBS items that are obsolete and should be removed from the MBS.
2. Consider identified priority reviews of selected MBS services.
3. Develop a program of work to consider the balance of MBS services within its remit and items assigned to the Committee.
4. Advise the Taskforce on relevant general MBS issues identified by the Committee in the course of its deliberations.

The recommendations from the Clinical Committees are released for stakeholder consultation. The Clinical Committees will consider feedback from stakeholders and then provide recommendations to the Taskforce in a Review Report. The Taskforce will consider the Review Report from Clinical Committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

The Diagnostic Imaging Clinical Committee (the Committee) was established in 2015 to make recommendations to the MBS Review Taskforce on the review of MBS items in its area of responsibility, based on rapid evidence review and clinical expertise. The Taskforce asked the Committee to review bone densitometry as a priority and the Committee established a Bone Densitometry Working Group (the Working Group) to undertake this priority review.

1.1 Areas of responsibility of the Bone Densitometry Working Group

The following seven MBS items were identified for review by the Bone Densitometry Working Group. A full list of items and descriptions are listed in Appendix B.

Bone Densitometry

Category 2 — Diagnostic procedures and investigations

Group — Diagnostic, other

Items — 12306, 12309, 12312, 12315, 12318, 12321, 12323

1.2 Key recommendations

Recommendation 1: New items for repeat testing with intervals

This recommendation refers to item number 12323.

The Working Group recommends the introduction of intervals for bone densitometry (currently MBS item 12323) for the measurement of bone mineral density, for a person aged 70 years or over. This would involve the introduction of two new items with defined intervals as follows:

- △ Normal or mild osteopenia (down to t score of -1.5) 1 scan every 5 years
- △ Moderate to marked osteopenia (T score of -1.5 to -2.5) 1 scan every 2 years

Recommendation 2: Proposed item descriptor DEXA

This recommendation refers to item numbers 12306, 12312, 12315, 12321 and 12323.

The Working Group recommends that, as has been usual historical practice, a radiation licence, from the relevant State or Territory jurisdiction is required to perform a dual-energy x-ray absorptiometry (DEXA) scan, under the supervision of an appropriate specialist or consultant physician.

Recommendation 3: Proposed item descriptor QCT

This recommendation refers to item numbers 12309 and 12318.

The Working Group recommends medical radiation practitioners should perform QCT scans under the supervision of an appropriate specialist or consultant physician, which could be on or off site, but would include the ability to provide contemporary/real time review of images as they were produced to ensure adequacy.

Recommendation 4: Interpretation and report provided by a specialist or consultant physician

This recommendation refers to item numbers 12306, 12309, 12312, 12315, 12318, 12321 and 12323.

The Working Group recommends the interpretation and report for bone densitometry services must be provided by a specialist or consultant physician.

Recommendation 5: Site measurements for QCT and DEXA items

The Working Group recommends the Department undertake further work to determine the most appropriate way to include the measurement of spine and hip in the item descriptor for QCT and DEXA items.

1.3 Consumer engagement

The Working Group did not have a consumer representative. The Working Group recommendations have been summarised for consumers in Appendix A. The consumer items table describes the medical service, the recommendation of the clinical experts and why the recommendation has been made.

Importantly however, the Working Group and the Committee believe it is important to find out from consumers if they will be helped or disadvantaged by the recommendations – and how, and why. Following the public consultation the Committee will assess the advice from consumers and decide whether any changes are needed to the recommendations. The Committee will then send the recommendations to the MBS Taskforce. The Taskforce will consider the recommendations as well as the information provided by consumers in order to make sure that all the important concerns are addressed. The Taskforce will then provide the recommendations to government.

The review of bone densitometry identified a number of issues:

- △ Changes in bone loss cannot be reliably measured by yearly testing
- △ Testing should only be performed by appropriately qualified technicians
- △ Testing on specific parts of the body, hip and spine, give the most accurate results

The proposed changes to the MBS will improve the accuracy and quality of care being provided to patients.

2. About the Medicare Benefits Schedule (MBS) Review

2.1 Medicare and the MBS

What is Medicare?

Medicare is Australia's universal health scheme which enables all citizens (and some overseas visitors) to have access to a wide range of health services and medicines at little or no cost.

Introduced in 1984, Medicare has three components, being free public hospital services for public patients, subsidised drugs covered by the Pharmaceutical Benefits Scheme, and subsidised health professional services listed on the Medicare Benefits Schedule (MBS).

What is the Medicare Benefits Schedule (MBS)?

The Medicare Benefits Schedule (MBS) is a listing of the health professional services subsidised by the Australian government. There are over 5,700 MBS items which provide benefits to patients for a comprehensive range of services including consultations, diagnostic tests and operations.

2.2 What is the MBS Review Taskforce?

The government has established a Medicare Review Taskforce to review all of the 5,700 MBS items to ensure they are aligned with contemporary clinical evidence and practice and improve health outcomes for patients.

What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key goals:

- △ **Affordable and universal access**— the evidence demonstrates that the MBS supports very good access to primary care services for most Australians, particularly in urban Australia. However, despite increases in the specialist workforce over the last decade, access to many specialist services remains problematic with some rural patients being particularly under-served.
- △ **Best practice health services**— one of the core objectives of the Review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base where possible. Although the Medical Services Advisory Committee (MSAC) plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items pre-dates this process and has never been reviewed.
- △ **Value for the individual patient**—another core objective of the Review is to have a MBS that supports the delivery of services that are appropriate to the patient's needs, provide real clinical value and do not expose the patient to unnecessary risk or expense.
- △ **Value for the health system**—achieving the above elements of the vision will go a long way to achieving improved value for the health system overall. Reducing the volume of services that provide little or no clinical benefit will enable resources to be redirected to new and existing services that have proven benefit and are underused, particularly for patients who cannot readily access those services currently.

2.3 Methods: The Taskforce's approach

The Taskforce is reviewing the existing MBS items, with a primary focus on ensuring that individual items and usage meet the definition of best practice.

Within the Taskforce's brief there is considerable scope to review and advise on all aspects which would contribute to a modern, transparent and responsive system. This includes not only making recommendations about new items or services being added to the MBS, but also about a MBS structure that could better accommodate changing health service models.

The Taskforce has made a conscious decision to be ambitious in its approach and seize this unique opportunity to recommend changes to modernise the MBS on all levels, from the clinical detail of individual items, to administrative rules and mechanisms, to structural, whole-of-MBS issues.

The Taskforce will also develop a mechanism for the ongoing review of the MBS once the current Review is concluded.

As the Review is to be clinician-led, the Taskforce has decided that the detailed review of MBS items should be done by Clinical Committees. The Committees are broad based in their membership and members have been appointed in their individual capacity, not as representatives of any organisation. This draft report details the work done by the specific Clinical Committee and describes the Committee's recommendations and their rationale.

This report does not represent the final position of the Diagnostic Imaging Clinical Committee on the recommendations of the Bone Densitometry Working Group. A consultation process will inform recommendations of the Working Group and assist the Committee in finalising its report to the MBS review Taskforce.

Following consultation, the Diagnostic Imaging Clinical Committee will provide its final advice to the MBS Review Taskforce. The Taskforce will consider the Review Report from Clinical Committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

2.4 Prioritisation process

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of and timeframe for the Review, each Clinical Committee has needed to develop a work plan and assign priorities keeping in mind the objectives of the Review. With a focus on improving the clinical value of MBS services, the Clinical Committees have taken account of factors including the volume of services, service patterns and growth and variation in the per capita use of services, to prioritise their work.

In addition to MBS data, important resources for the Taskforce and the Clinical Committees have included:

- △ The Choosing Wisely recommendations, both from Australian and internationally
- △ National Institute for Health and Care Excellence (NICE UK) Do Not Do recommendations and clinical guidance

- △ Other literature on low value care, including Elshaug et al's¹ Medical Journal of Australia article on potentially low value health services
- △ The Australian Commission on Quality and Safety in Health Care's (ACQSHC) Atlas of Clinical Variation

3. About the Bone Densitometry Working Group

The Bone Densitometry Working Group was established by the Committee to review bone densitometry items.

3.1 Diagnostic Imaging Clinical Committee members

Table 1: Diagnostic Imaging Clinical Committee Members

Name	Position/Organisation	Declared conflict of interest
Professor Ken Thomson (Chair)	Program Director, Radiology and Nuclear Medicine, Alfred Hospital	User of MBS services
Professor Stacy Goergen	Director of Research, Monash Imaging; Clinical Adjunct Professor, Southern Clinical School, Monash University	User of MBS services
Professor Alexander Pitman	Director of Nuclear Medicine and PET, Lake Imaging ;Adjunct Professor, Medical Imaging, University of Notre Dame	User of MBS services
Dr William Macdonald	Executive Director, Imaging West Head, Nuclear Medicine, Fiona Stanley Hospital; President, Australasian Association of Nuclear Medicine Specialists	User of MBS services
Dr Richard Ussher	Director of Training, Radiology, Ballarat Health Services; Director, Grampians BreastScreen	User of MBS services
Dr Walid Jammal	Clinical Lecturer, Faculty of Medicine, University of Sydney; Conjoint Senior Lecturer, School of Medicine, University of Western Sydney; Private practice	User of MBS services
Associate Professor Rachael Moorin	Associate Professor, Health Policy & Management, School of Public Health, Curtin University; Principal Researcher, Health Centre of Excellence, Silver Chain Group; Adjunct Associate Professor, University of Western Australia	Nil
Dr David Brazier	Radiologist, Royal North Shore Hospital	User of MBS services
Dr Phil Hayward	Research Fellow, Centre for Health Economics Research and Evaluation	Nil

Name	Position/Organisation	Declared conflict of interest
Professor Jenny Doust	Professor of Clinical Epidemiology, Centre for Research in Evidence Based Practice, Bond University; General Practitioner	User of MBS services
Ms Geraldine Robertson	Consumer Representative, Consumers Health Forum & Breast Cancer Network Australia	Nil
Dr Bastian Seidel	Director, Huon Valley Health Centre; Clinical Professor, Faculty of Health, University of Tasmania; Chair, Tasmanian Faculty, The Royal Australian College of General Practitioners; General Practitioner, Private practice	User of MBS services
Dr Matthew Andrews	MBS Review Taskforce (Ex-Officio)	User of MBS services

3.2 Bone Densitometry Working Group members

Table 2: Bone Densitometry Working Group Members

Name	Position/Organisation	Declared conflict of interest
Professor Rachael Moorin (Chair)	Professor, Health Systems & Economics, School of Public Health, Curtin University; Principal Investigator, Health Centre of Excellence, Silver Chain Group	Nil
Dr William Macdonald	Executive Director, Imaging West; Head, Nuclear Medicine, Fiona Stanley Hospital; President, Australasian Association of Nuclear Medicine Specialists	User of MBS services
Dr Walid Jammal	Clinical Lecturer, Faculty of Medicine, University of Sydney; Conjoint Senior Lecturer, School of Medicine, University of Western Sydney; Private practice	User of MBS services
Dr Peter Downey	Flinders Southern Adelaide Clinical School, Medical Imaging, Flinders University	User of MBS services
Dr Merle Wigeson	Diagnostic Radiologist, PRS	User of MBS services
A/Professor Nicholas Pocock	Senior Staff Specialist, Nuclear Medicine, St Vincent's Hospital; Associate Professor, University of New South Wales	Interest in a bone densitometry business; user of MBS services
Dr Simon Vanlint	Senior lecturer, Discipline of General Practice, University of Adelaide; Private practice	User of MBS services

3.3 Conflicts of interest

All members of the Taskforce, Clinical Committees and Working Groups are asked to declare any conflicts of interest at the start of their involvement and reminded to update their declarations periodically.

3.4 Meeting dates

The Clinical Committee met on 23 October 2015 and 20 November 2015.

4. Areas of responsibility of the Bone Densitometry Working Group

The following seven MBS items, listed in Table 3, were identified for review by the Working Group.

Table 3: List of MBS items identified for review by the Bone Densitometry Working Group

Item	Short Descriptor
12306	Bone densitometry using DEXA for confirmation of low bone mineral density
12309	Bone densitometry using QCT for confirmation of low bone mineral density
12312	Bone densitometry using DEXA for diagnosis and monitoring of bone loss, specified conditions
12315	Bone densitometry using DEXA for diagnosis and monitoring of bone loss, specified conditions
12318	Bone densitometry using QCT for diagnosis and monitoring of bone loss, specified conditions
12321	Bone densitometry using DEXA for measurement of bone density
12323	Bone densitometry using DEXA or QCT for measurement of bone mineral density, patient aged 70 or more

5. Issues identified

5.1 Background to review of Bone Densitometry

The principal purpose of this review was to consider:

- △ Whether an interval should be prescribed for the screening service for a person aged 70 years or older (item 12323)
- △ Whether there is value in recrafting the items and/or consolidating them
- △ Whether there is a need to define the qualifications of the person who performs the service and what should those qualifications be
- △ Whether other aspects of the current Bone Mineral Densitometry (BMD) items should undergo an evidence review.

There are seven MBS BMD items. The most commonly used item (12323) is for screening of people over 70 years old and is the only BMD item that has no interval restriction (other items have 12 months/24 months restrictions). The Medical Services Advisory Committee (MSAC) has recently recommended against extending screening to people under 70 years old. In addition, MSAC supported amending the current MBS items for BMD to allow trained technicians to perform DEXA scanning under the supervision of a medical practitioner and recommended that MBS fee to be reduced in response.

The [Choosing Wisely recommendations from Canada and the USA](#) suggest restricting the use of DEXA screening for osteoporosis on low risk patients, and restricting repeat of DEXA scans to no more often than every two years in the absence of high risk or new risk factors.

5.2 MBS context

In June 1993, the Minister for Health asked the Medicare Benefits Advisory Committee (MBAC) to consider whether a determination under section 3C of the *Health Insurance Act 1973* should be made for bone densitometry. MBAC based its recommendations on those provided by the Australian and New Zealand Bone and Mineral Society (ANZBMS) and the Minister introduced two densitometry items by 3C determination for a 12 month trial period.ⁱⁱ

Over time, further items were added to the MBS and in 2004, the six MBS items related to bone densitometry were referred to MSAC for re-assessment. A literature review was performed but no changes were made to the existing MBS items.ⁱⁱⁱ

In 2006, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended listing of alendronate for the primary prevention of osteoporosis in men and women aged over 70 years, with BMD T-score ≤ -3.0 .^{iv} Osteoporosis Australia requested that MSAC approve BMD testing in this population.ⁱⁱⁱ Item 12323 was introduced to the MBS in 2007.

6. Rationale to support recommendations

6.1 MBS data on bone densitometry

Tables –11 provide MBS data on the bone densitometry items used in the review.

Table 4: MBS Item number key information

MBS item number	Type of date	Date ^{iv}
12306, 12309,	Item Start Date	01-08-96
12312, 12315,	Current Descriptor Start Date	01-08-96
12318, 12321	Current Schedule Fee Start Date	01-11-12
	Item Start Date	01-04-07
12323	Current Descriptor Start Date	01-12-07
	Current Schedule Fee Start Date	01-11-12

Table 5: High level MBS statistics (Date of Processing) for seven MBS item numbers

Statistic	12306	12309	12312	12315	12318	12321	12323
Services 2014/15	88,559	1,492	65,335	34,641	1,830	18,652	192,498
Benefits 2014/15	\$7.8 m	\$130,726	\$5.7 m	\$3.0 m	\$159,394	\$1.6 m	\$16.8 m
Change in benefits (2011/12 – 2014/15)	9.4%	10.3%	7.9%	19.2%	54.6%	16.4%	46.4%
Number of patients	88,572	1,493	65,282	34,638	1,830	18,526	191,032
Number of providers	1,781	129	1,656	1,532	142	1,205	1,863

Source: Unpublished data (Department of Health)

Table 6: MBS item 12323 - Service distribution per patient within a one year period (2014-15, Date of Processing)

Services per patient	Number of patients*	Percentage of patients*
1	189,565	99.2%
2	1,454	0.8%
3	13	0.0%
Total	191,032	100.0%

*Patients have been counted in a reference period where they have had claims for at least one item 12323 service processed. Source: Unpublished data (Department of Health)

Table 7: MBS item 12323 - Patient services distribution for males by patient age (2014-15, Date of Processing)

Patient age	1 service per patient	2 – 3 services per patient	Total
65 - 69	2,380	7	2,387
70 - 74	19,629	111	19,740
75 - 79	17,115	110	17,225
80 - 84	11,094	94	11,188
85 +	5,736	38	5,774
Total	55,954	360	56,314

Source: Unpublished data (Department of Health)

Table 8: MBS item 12323 - Patient services distribution for females by patient age (2014-15, Date of Processing)

Patient age	1 service per patient	2 – 3 services per patient	Total
65 - 69	7,344	32	7,376
70 - 74	50,212	389	50,601
75 - 79	39,045	377	39,422
80 - 84	24,038	211	24,249
85 +	12,972	98	13,070
Total	133,611	1,107	134,718

Source: Unpublished data (Department of Health)

Table 9: MBS item 12323 - Service distribution per patient within a two year period (2013-14 to 2014-15, Date of Processing)

Services per patient	Patients*	Percentage
1	316,892	94.0%
2	19,928	5.9%
3	322	0.1%
4 - 5	14	0.0%
Total	337,156	100.0%

*Patients have been counted in a reference period where they have had claims for at least one item 12323 service processed. **Unpublished data (Department of Health)**

Table 10: MBS item 12323 - Patient service distribution for males within a two year period by age (2013-14 to 2014-15, Date of Processing)

Patient age	1 service per patient	2 services per patient	3+ services per patient	Total
65 - 69	2,381	6	<5	2,388
70 - 74	32,090	1,708	21	33,819
75 - 79	29,069	1,827	21	30,917
80 - 84	19,504	1,203	22	20,729
85 +	10,609	639	10	11,258
Total	93,653	5,383	75	99,111

Source: Unpublished data (Department of Health)

Table 11: MBS item 12323 - Patient service distribution for females within a two year period by age (2013-14 to 2014-15, Date of Processing)

Patient age	1 service per patient	2 services per patient	3+ services per patient	Total
65 - 69	7,344	32	0	7,376
70 - 74	82,408	5,101	86	87,595
75 - 79	66,870	5,003	101	71,974
80 - 84	42,189	2,971	48	45,208
85 +	24,431	1,435	26	25,892

Patient age	1 service per patient	2 services per patient	3+ services per patient	Total
Total	223,242	14,542	261	238,045

Source: Unpublished data (Department of Health)

The majority of patients only had one service in 2014-15. Over a 2-year period from 2013-14 to 2014-15, there were 1,467 patients who had more than one 12323 BMD service in 2014-15, and 20,264 patients (6% of all patients who had a 12323 BMD service) who had more than one service over the 2 year period.

6.2 Who can perform Bone Densitometry Services?

Since the introduction of BMD items onto the MBS, for Medicare purposes, BMD services must be personally performed by a specialist or consultant physician (in the practice of his or her specialty). This means for a Medicare benefit to be payable, a technician cannot perform a service billed by a specialist/consultant physician.

The 2013 Department of Human Services (DHS) Program Review Division undertook an Audit of Diagnostic Procedures and Investigations including 'Bone Densitometry' and examined bone densitometry services performed by 21 practices in 2011-12.

DHS expressed concerns at the level of uptake of item 12323, as it appeared a large proportion of the 328,818 bone densitometry services claimed in 2011-12 were performed by technicians. They cited anecdotal evidence that suggests that the specialists billing these items (across the profession) are not personally performing the scan as required under the regulations.

6.3 Stakeholder feedback

As a result of compliance action by DHS, a number of stakeholders raised concerns about the current requirement that BMD services must be personally performed by a specialist or consultant physician and suggested that this has never been best practice in BMD examinations. There are no international or national guidelines which recommend that BMD services are performed by a specialist or consultant physician.

Feedback was provided by:

- △ Royal Australian and New Zealand College of Radiologists
- △ Australian New Zealand Bone & Mineral Society together with the Australian Rheumatology Association and the Endocrine Society of Australia.

At the November 2014 meeting, MSAC assessed a number of BMD-related applications. In MSAC's advice to the Minister, it supported amending the current MBS items for BMD to allow trained technicians to perform DEXA scanning under the supervision of a medical practitioner. MSAC considered that any amendment should be accompanied by a reduction in the MBS fee.

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 the identification of ‘appropriately trained’ technicians.

6.4 Appropriately trained technicians

There is no nationally agreed definition of an ‘appropriately trained’ technician. The [Australian and New Zealand Bone and Mineral Society \(ANZBMS\) 2003 accreditation guidelines for bone densitometry](#) requires a technologist in bone densitometry to be tertiary educated (degree or diploma) in the field of radiography, nuclear medicine, science or nursing, and must have additional post-graduate training in bone densitometry. Staff performing Quantitative Computed Tomography (QCT) must be trained radiographers.

The guidelines list the duties of a technologist and include patient scanning, scan analysis and reviewing of results. In addition, they must perform or supervise all quality control procedures and personally review results. Training of the technologist shall include at least the following elements:

- △ Appropriate tertiary qualifications as noted above
- △ Radiation safety (hazard analysis, regulations, patient advice, licensing)
- △ Patient management (reception, advising, lifting etc.)
- △ DXA (and/or QCT) scanning training
- △ DXA (and/or QCT) quality assurance and equipment performance
- △ Relevant statistical analysis and report generation.

Licences to operate ionising radiation equipment are a State issue and therefore the requirements vary across States and Territories. Generally, State and Territory law requires the licensee to possess the appropriate knowledge of the principles and practices of radiation protection relevant to the intended use of the licence. Specific licences exist for bone mineral or body composition analysis, using dual energy x-ray absorptiometry machines, with specific pre requisites and DEXA course requirements.

ANZBMS offers two-day clinical densitometry courses which satisfies the requirements of radiation safety legislation in most Australian states and the Australian Radiation Protection and Nuclear Safety Agency for licencing of DEXA operators. These courses are intended for both practitioners and technologists and cover the patho-physiology of osteoporosis, as well as the principles and practice of bone density, body composition measurement and aspects of advanced bone measurement techniques.

The Australian Institute of Radiology also runs a two-day certification course in clinical bone densitometry for technologists on behalf of the International Society for Clinical Densitometry.

6.5 Service restrictions

For Medicare purposes, most bone density testing is subject to a restriction on the time interval between tests, from one every 12 to 24 months, depending on the item. This is because bone density loss is considered a relatively slow process and repeat testing within 24 months is unlikely to assist in clinical decision making. For those specific medical conditions or particular treatments that

may cause more rapid bone loss, a rebate is available for repeat testing at 12 monthly intervals. Testing for people over the age of 70 years is currently not restricted to these intervals.

6.6 International Recommendations

Choosing Wisely

The Choosing Wisely recommendations relate to restricting the use of DEXA screening for osteoporosis on low risk patients, and restricting repeat of DEXA scans to no more than every two years in the absence of high risk or new risk factors.

The College of Family Physicians of Canada and Canadian Medical Association

Don't order DEXA screening for osteoporosis or low risk patients. While all patients aged 50 years and older should be evaluated for risk factors for osteoporosis using tools such as the osteoporosis self-assessment screening tool (OST), bone mineral density screening via DEXA is not warranted on women under 65 or men under 70 at low risk.

Canadian Rheumatology

Don't repeat dual energy X-ray absorptiometry (DEXA) scans more often than every two years.

The use of repeat DEXA scans at intervals of every two years is appropriate in most clinical settings, and is supported by several current osteoporosis guidelines. Because of limitations in the precision of testing, a minimum of two years may be needed to reliably measure a change in BMD. If bone mineral densities are stable and/or individuals are at low risk of fracture, then less frequent monitoring up to an interval of 5-10 years can be considered. Shorter or longer intervals between repeat DEXA scans may be appropriate based on expected rate of change in bone mineral density and fracture risk.

The Canadian Association of Nuclear Medicine

Don't repeat DEXA scans more often than every two years in the absence of high risk or new risk factors.

Various factors limit the utility of repeat DEXA scans more than every two years, particularly in stable patients. These include the expected rate of bone loss, which is unlikely to be detected at smaller intervals, and measurement error, which may make repeat measures unreliable. This may be compounded if different DEXA machines are used. In stable patients, the interval between scans may be prolonged, or a repeat may not be necessary.

7. Recommendations

The Bone Densitometry Working Group considered a series of questions and issues in order to review the Bone Densitometry items especially current items descriptors and items structure in order to reduce its complexity and improve clarity.

7.1 Intervals for repeat testing for bone densitometry MBS item 12323

The Working Group recommended that an interval restriction be imposed on item 12323. It was noted that when osteoporosis is diagnosed, future testing would occur using other relevant bone densitometry item numbers as the patient would then be eligible to access those item numbers.

It was agreed that a testing interval of 1 year was not reliable to detect change attributable to actual bone loss in the screening setting.

This would involve the introduction of new items.

Recommendation 1: New items for repeat testing with intervals

Working Group members agreed to the following intervals and new items:

- △ Normal or mild osteopenia (down to T Score of -1.5) 1 scan every 5 years
- △ Moderate to marked osteopenia (T Score of -1.5 to -2.5) 1 scan every 2 years

The Working Group considered several research papers to inform their decision including Frost et al 2009 and Goulay 2012. See Appendix C for more detailed discussion.

Following are the draft items descriptors (please note these item descriptors are draft only and may be amended prior to implementation).

Table 12: Draft item descriptors

Item	Descriptor
Item No XXXXX	<ul style="list-style-type: none">△ Bone densitometry using dual energy X-ray absorptiometry or quantitative computerised tomography, for the measurement of bone mineral density, for a person aged 70 years or over with normal or mild osteopenia.△ Measurement of 2 or more sites - 1 service only in a period of 60 consecutive months - including interpretation and report; not being a service associated with a service to which item 12306, 12309, 12312, 12315, 12318, 12321 or XXXXX applies (Ministerial Determination).
Item No XXXXX	<ul style="list-style-type: none">△ Bone densitometry using dual energy X-ray absorptiometry or quantitative computerised tomography, for the measurement of bone mineral density, for a person aged 70 years or over with moderate to marked osteopenia.△ Measurement of 2 or more sites - 1 service only in a period of 24 consecutive months - including interpretation and report; not being a service associated with a service to which item 12306, 12309, 12312, 12315, 12318, 12321 or XXXXX applies (Ministerial Determination).

The definition of 'normal or mild' and 'moderate to marked' osteopenia, including the T score will be provided in the explanatory note.

Introduction of an upper age limit for Bone Densitometry items

The Working Group discussed whether to introduce an upper age limit for this item. Members noted that there is no evidence to support this and that the Pharmaceutical Benefits Scheme does not have an upper age limit to access treatment. For this reason it was agreed that there should be no upper age limit introduced for this item.

Fees for Bone Densitometry items

The Working Group also discussed the recent MSAC recommendations in relation to Medicare funded BMD services. The Working Group did not support any reduction in the schedule fee due to proposed changes to the regulations about the personnel conducting the BMD test. The Working Group agreed that the current fee is reasonable given the level of work required to provide a best practice bone densitometry service. The Working Group also highlighted concerns about a potential fee decrease impacting on the ability of services to provide bone densitometry examinations and the potential for this to lead to patients not accessing services.

7.2 Performance of Medicare funded bone densitometry services

Since BMD was included on the MBS in 1994, the items have required that the service be personally performed by a specialist or consultant physician (in the practice of his or her speciality).

At the November 2014 meetings MSAC assessed a number of BMD related applications and in its advice to the Minister, supported amending the BMD items to allow trained technicians to perform a DEXA scan. In order to define what a trained technician should be, it was decided that state and territory licensing requirements could be used.

The Bone Densitometry Working Group noted that it is not currently standard practice, and has not been usual historical practice, for specialists or consultant physicians to perform DEXA scans. Working Group members advised that in line with best practice in the USA and Europe it is the usual practice that DEXA is performed by technologists and reported by a qualified specialist or consultant physician.

State and territory radiation licenses

Each state and territory has licence requirements for the operation of a radiation apparatus and requires the licensee to complete specific bone densitometry training courses, such as the Australian and New Zealand Bone Mineral Society / Densitometry training or the InMed Pty Ltd / DEXA radiation safety course.

The Working Group agreed that the state and territory radiation licence requirements provided a level of certainty and training required for those performing bone densitometry services and recommended that the item descriptor for Medicare-funded DEXA services should reflect the licence requirements for the person performing the services.

State and territory law requires people who use radiation apparatuses to demonstrate to that they have appropriate knowledge of the principles and practices of radiation safety and protection, and experience applicable to the activities proposed to be carried out, in order to hold a radiation

licence. Licence condition codes exist for bone mineral or body composition analysis, using dual energy x-ray absorptiometry machines, with specific pre requisites and DEXA course requirements.

Recommendation 2: Proposed item descriptor dual energy X ray absorptiometry (DEXA) (items 12306, 12312, 12315, 12321 and 12323)

The proposed item descriptor for Medicare-funded DEXA services reflect the licence requirements for the person performing the services and that the interpretation and report must be provided by a specialist or consultant physician.

Bone densitometry (performed by a person who holds a radiation licence under a law of a State or Territory, who is under the supervision of a medical practitioner and where the patient is referred by another medical practitioner), using dual energy X ray absorptiometry, for:

Measurement of 2 or more sites – X service only in a period of XX months including interpretation and report by a specialist or consultant physician; not being a service associated with a service to which item XX applies.

Recommendation 3: Proposed item descriptor quantitative computerised tomography (QCT) (items 12309 and 12318)

The Working Group agreed that medical radiation practitioners should perform QCT scans under the supervision of an appropriate specialist or consultant physician, which could be on or off site, but would include the ability to provide contemporary/real time review of images as they were produced to ensure adequacy.

It was agreed by the Working Group that the proposed item descriptor for Medicare-funded QCT services reflect the qualification requirements for the person performing the services and that the interpretation and report must be provided by a specialist or consultant physician.

Bone densitometry (performed by a person registered as a medical radiation practitioner under a law of a State or Territory, where the patient is referred by another a medical practitioner), using quantitative computerised tomography, for:

Measurement of 2 or more sites – X service only in a period of XX months including interpretation and report by a specialist physician or consultant physician; not being a service associated with a service to which item XX applies.

Recommendation 4: Interpretation and report provided by a specialist or consultant physician (items 12306, 12309,12312,12315,12318,12321 and 12323)

Members also agreed that the interpretation and report must be provided by a specialist or consultant physician. Members discussed whether the specialist or consultant physician providing the report and interpretation should have specific bone densitometry training or other requirements, and whether this should be included in the item descriptor.

The Working Group agreed that Colleges would be in the best position to address this. It was agreed that there should be a requirement that the specialist or consultant physician providing the report

and interpretation should have training in DEXA provision as considered appropriate by their relevant college.

7.3 Site Measurements for QCT and DEXA Items

Members also discussed, in relation to the QCT and DEXA items, whether to specify that the two or more sites listed in the item descriptor should include spine and hip. Members discussed the exceptions to this and agreed for the Department of Health to investigate the most appropriate way of addressing this in the regulations.

This issue is currently addressed in the Bone Densitometry explanatory notes where it states that:

An examination under any of these items covers the measurement of 2 or more sites, interpretation and provision of a report; all performed by a specialist or consultant physician in the practice of his or her specialty. Two or more sites must include the measurement of bone density of the lumbar spine and proximal femur. If technical difficulties preclude measurement at these sites, other sites can be used for the purpose of measurements. The measurement of bone mineral density at either forearms or both heels or in combination is excluded for the purpose of Medicare benefit.

Recommendation 5: Site measurements for QCT and DEXA items

Members agreed that the Department will undertake further work to determine the most appropriate way to include the measurement of spine and hip in the item descriptor for QCT and DEXA items.

8. Impact Statement

The introduction of an interval for repeat testing for item 12323 is expected to have minimal impact on providers or patients. Whilst patients over 70 will no longer be able to access Medicare funded BMD services annually, they will still be able to access clinically appropriate BMD services.

This change would align the arrangements for 12323 with other BMD items, which already have repeat testing intervals.

The recommendations around the level of qualifications an operator should not have an impact on providers or patients as DEXA operators are already required by State and Territory regulations to have this level of qualification in order to perform the service.

9. References

This contains references to sources and materials referenced in this report.

- i. Elshaug A, et al (2012). Over 150 potentially low-value health care practices: an Australian study. Medical Journal of Australia; Vol.197 (10), 556-560.
- ii. Medicare Benefits Advisory Committee. October 2002. Minute to Medical Services Advisory Committee: MSAC Application No. 1060 Bone Mineral Densitometry Referral- Bone Densitometry
- iii. Medical Services Advisory Committee. [draft] Bone densitometry testing. July 2004. MSAC Reference 19.
- iv. Osteoporosis Australian. An Application for Increasing the Availability for BMD testing to at-risk groups. September 2006
- v. Department of Health. MBS Online.
<http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home> (accessed September 2015).

10. Glossary

Acronyms	Descriptions
ANZBMS	Australian and New Zealand Bone and Mineral Society
BMD	bone mineral densitometry
bone densitometry	An enhanced form of x-ray technology that is used to measure bone loss.
Department, The	Australian Government Department of Health
DEXA	dual-energy x-ray absorptiometry
DHS	Australian Government Department of Human Services
Low-value care	The use of an intervention which evidence suggests confers no or very little benefit on patients, or that the risk of harm exceeds the likely benefit, or, more broadly, that the added costs of the intervention do not provide proportional added benefits.
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, comprising an item number, service descriptor and supporting information, Schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure, test to which the relevant MBS item refers.
MSAC	Medical Services Advisory Committee
Obsolete services	Services that should no longer be performed as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
OST	osteoporosis self-assessment screening tool
osteopenia	Osteopenia refers to bone density that is lower than normal peak density but not low enough to be classified as osteoporosis
osteoporosis	Osteoporosis is a condition that affects the bones, causing them to become weak and fragile and more likely to break (fracture). These fractures most commonly occur in the spine, wrist and hips, but can affect other bones such as the spine, arm or pelvis.
QCT	Quantitative Computed Tomography

Appendix A - Summary for Consumers

Bone densitometry Working Group recommendations

This table describes the medical service, recommendations of the Clinical Experts and why the recommendation has been made.

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Item	What it does	Committee Recommendation	What would be different	Why
12323 – bone densitometry, for a person aged 70 years or over.	Measurement of bone mineral densitometry (BMD).	Repeat testing of BMD for patients with normal or mild osteopenia can occur once every 5 years, and repeat testing for patients with moderate or marked osteopenia can occur once every 2 years.	There is currently no restriction on how often BMD is measured. It should be noted that patients diagnosed with osteoporosis are not affected by these changes; future testing would occur using other relevant bone densitometry item numbers specifically for patients with osteoporosis.	Yearly testing is not reliable to detect changes in bone loss. This finding was supported by evidence.

Recommendation 2, 3 and 4: All BMD items that use Dual energy X-ray (DEXA) scans.

Item	What it does	Committee Recommendation	What would be different	Why
<p>All BMD items that use Dual energy X-ray (DEXA) scans.</p>	<p>This is a technology used to determine BMD.</p>	<p>A radiation licence, from the relevant State or Territory jurisdiction is required to perform a DEXA scan under the supervision of an appropriate specialist or consultant physician.</p>	<p>Instead of a specialist or consultant physician, a specifically licenced and qualified technician would be required to perform the DEXA scan.</p>	<p>Since BMD was included on the MBS in 1994, the items have required that the service be personally performed by a specialist or consultant physician. DEXA scan technology was recommended for inclusion in MBS items for BMD in November 2014.</p> <p>It is not currently standard practice for specialists or consultant physicians to perform DEXA scans. It is best practice in the US and Europe that DEXA is performed by trained technicians and reported by specialists or consultant physicians.</p>

Recommendation 5: All BMD items which specify measurement of 2 or more sites.

Item	What it does	Committee Recommendation	What would be different	Why
All BMD items which specify measurement of 2 or more sites.	Different parts of the body can be used to measure BMD and the MBS items request 2 or more sites be measured.	Specifying that measurement should include spine and hip.	This is currently stated in explanatory notes to the BMD MBS items, but to be enforceable it would need to go into regulations.	The most reliable BMD measures come from the spine and hip.

Appendix B - Bone densitometry MBS items assigned to Bone Densitometry Working Group for review

Item 12306

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 confirmation of a presumptive diagnosis of low bone mineral density made on the basis of 1 or more fractures occurring after minimal trauma; or

- for the monitoring of low bone mineral density proven by bone densitometry at least 12 months previously.

Measurement of two or more sites - **one service only in a period of 24 months** - including interpretation and report; not being a service associated with a service to which item 12309, 12312, 12315, 12318 or 12321 applies (Ministerial Determination)

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Item 12309

Bone densitometry (performed by a specialist or consultant physician where the patient is referred by another medical practitioner), using quantitative computerised tomography, for:

- the confirmation of a presumptive diagnosis of low bone mineral density made on the basis of 1 or more fractures occurring after minimal trauma; or
- for the monitoring of low bone mineral density proven by bone densitometry at least 12 months previously.

Measurement of two or more sites - **one service only in a period of 24 months** - including interpretation and report; not being a service associated with a service to which item 12306, 12312, 12315, 12318 or 12321 applies (Ministerial Determination)

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Item 12312

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 diagnosis and monitoring of bone loss associated with 1 or more of the following conditions:

- prolonged glucocorticoid therapy;

- conditions associated with excess glucocorticoid secretion;
- male hypogonadism; or
- female hypogonadism lasting more than six months before the age of 45.

Where the bone density measurement will contribute to the management of a patient with any of the above conditions - measurement of two or more sites - **one 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, 12315, 12318 or 12321 applies (Ministerial Determination)

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Item 12315

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 diagnosis and monitoring of bone loss associated with one or more of the following conditions:

- primary hyperparathyroidism;
- chronic liver disease;
- chronic renal disease;
- proven malabsorptive disorders;
- rheumatoid arthritis; or
- conditions associated with thyroxine excess.

Where the bone density measurement will contribute to the management of a patient with any of the above conditions - measurement of two or more sites - **one service only in a period of 24 consecutive months** - including interpretation and report; not being a service associated with a service to which item 12306, 12309, 12312, 12318 or 12321 applies (Ministerial Determination)

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Item 12318

Bone densitometry (performed by a specialist or consultant physician where the patient is referred by another medical practitioner), **using quantitative computerised tomography**, for the diagnosis and monitoring of bone loss associated with one or more of the following conditions:

- prolonged glucocorticoid therapy;
- conditions associated with excess glucocorticoid secretion;
- male hypogonadism;
- female hypogonadism lasting more than six months before the age of 45;
- primary hyperparathyroidism;

- chronic liver disease;
- chronic renal disease;
- proven malabsorptive disorders;
- rheumatoid arthritis; or
- conditions associated with thyroxine excess.

Where the bone density measurement will contribute to the management of a patient with any of the above conditions - measurement of two or more sites - **one service only in a period of 24 consecutive months** - including interpretation and report; not being a service associated with a service to which item 12306, 12309, 12312, 12315 or 12321 applies (Ministerial Determination)

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Item 12321

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 density 12 months following a significant change in therapy for:

- established low bone mineral density; or
- the confirmation of a presumptive diagnosis of low bone mineral density made on the basis of 1 or more fractures occurring after minimal trauma.

Measurement of two or more sites - **one 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 or 12318 applies (Ministerial Determination).

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Item 12323

Bone densitometry (performed by a specialist or consultant physician where the patient is referred by another medical practitioner), **using dual energy X-ray absorptiometry or quantitative computerised tomography**, for the measurement of bone mineral density, for a person aged 70 years or over.

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

Fee: \$102.40

Benefit: 75% = \$76.80 85% = \$87.05

Appendix C - RAPID REVIEW: Dual energy x-ray absorptiometry

Research Questions

The key research questions for the evidence review of Dual Energy X-ray absorptiometry (DXA) are:

- △ In the absence of a predisposing condition, in which age groups is DXA useful as a screening tool to prevent fracture?
- △ What interval is recommended between serial DXA scans?
 - a) When used as a screening tool for patients >70 years
 - b) For the monitoring of an osteoporotic patient
- △ How effective is the FRAX algorithm in predicting fracture risk when compared to DXA?

Research Methods

A quick literature search using MEDLINE was performed to obtain relevant review articles for the research questions. From these articles, a list of major societies and regulating bodies on the topic were obtained to produce the tables of clinical guidelines. Their references were examined to obtain the main studies contributing to the body of knowledge. A series of literature reviews for specific research questions was then performed on MEDLINE to identify other studies for inclusion. Their reference lists were also examined for additional relevant studies not identified through the search.

Results of Research

In which age groups is DXA useful as a screening tool?

Studies

This research question must be addressed separately for women and men, as the availability of evidence is different.

Two studies were identified as relevant to the research question in a female population. One is not reported here as it was a retrospective cohort study¹ whose results (suggesting a correlation between DXA screening and reduced hip fractures) have been supplanted by those of a well-designed RCT. Barr et al.² have produced the only RCT identified to assess population screening with DXA and reduction of fracture risk. 4,800 women aged 45-54 were randomised in equal numbers to DXA screening or non-screening. Nine years later, they assessed the uptake of treatment and the incidence of fracture by postal questionnaire, with a response rate just over 60 per cent. They found that a significantly greater number of screened subjects reported current or past use of osteoporosis medications (69.0% vs 59.4%, $p < 0.001$). Using intention-to-treat analysis, the risk of fracture had been reduced by 20.9% in the screened group, but this was not significant (HR=0.791; 95%CI= 0.60-1.04; $p = 0.096$). However, using per-protocol analysis, which assessed the DXA screened women who attended their initial screening assessment and thus were informed of their DXA results, they found a significant 26.6 per cent reduction in all fractures (HR=0.734; 95%CI=0.55-0.99; $p = 0.04$) but a non-

significant result for the major fractures (hip, wrist, vertebra, humerus) (HR=0.724, 95%CI=0.47-1.13; p=0.15). The authors concluded that the study strongly suggests that a population screening programs for osteoporosis increases uptake of osteoporosis treatment and reduces overall fracture risk in those who participate. Their study is limited by its low participant response rate (60%), reliance on self-reported outcomes and limited age range of participants.

No studies were identified that evaluated the use of DXA scans for screening asymptomatic men of any age group.

Table C1: Clinical Practice Guidelines – age groups

Group, publishing date	Women	Men
<i>Royal Australian College of General Practitioners 2012</i>	△ Age >50: if they have additional clinical risk factors* perform DXA	△ Age >60: if they have additional clinical risk factors* perform DXA
<i>National Health and Medical Research Council (NHMRC) 2010**</i>	△ Age >70: recommended △ Age 60-70: recommended if they have risk factors* △ Age 50-60: recommended if they have a vertebral fracture or peripheral fracture as an individual case decision	△ Age >70: recommended △ Age 60-70: recommended if they have risk factors* △ Age 50-60: recommended if they have a vertebral fracture or peripheral fracture as an individual case decision
<i>United States Preventive Services Task Force (USPSTF) 2011</i> <i>Note: currently updating 2011 Guidelines</i>	△ Age ≥65: recommended △ Age <65: recommended where fracture risk is equivalent to a 65 year old (based on FRAX algorithm)	△ Does not recommend screening (insufficient evidence)
<i>National Osteoporosis Foundation (NOF) 2014</i>	△ Age ≥65: recommended △ Postmenopausal women <65: DXA considered if they have a high risk factor profile*	△ Age ≥70: recommended △ Aged 50-69: DXA considered if they have a high risk factor profile*
<i>International Society for Clinical Densitometry (ISCD) 2015</i>	△ Age ≥65: recommended △ Age <65: DXA considered if they have a high risk factor profile*	△ Age ≥70: recommended △ Aged <70: DXA considered if they have a high risk factor profile*
<i>American College of Physicians (ACP) 2014</i>	△ Age ≥65: recommended △ Age <65: DXA considered if they have a high fracture risk (FRAX algorithm)	△ Age ≥75 recommended △ Age <75: DXA considered if they have a high fracture risk (FRAX algorithm)
<i>Canadian Medical Association (CMA) 2010</i>	△ Age ≥65: recommended	△ Age ≥65: recommended

Group, publishing date	Women	Men
	<ul style="list-style-type: none"> △ Age 50-64: DXA considered if they have a high risk factor profile* 	<ul style="list-style-type: none"> △ Age 50-64: DXA considered if they have a high risk factor profile*
<i>National Osteoporosis Guideline Group***</i> 2014	<p><i>Perform FRAX in:</i></p> <ul style="list-style-type: none"> △ Postmenopausal women with a risk factor* △ Men aged >50 with a risk factor* <p><i>If high risk, initiate treatment. If intermediate risk, refer for DXA. If low risk, reassure and reassess in 5 years or less if needed.</i></p>	<p><i>Perform FRAX in:</i></p> <ul style="list-style-type: none"> △ Postmenopausal women with a risk factor* △ Men aged >50 with a risk factor* <p><i>If high risk, initiate treatment. If intermediate risk, refer for DXA. If low risk, reassure and reassess in 5 years or less if needed.</i></p>
<i>National Clinical Guideline Centre UK</i> 2012	<p><i>Consider performing FRAX or QFracture assessment in all:</i></p> <ul style="list-style-type: none"> △ Women ≥65 and men ≥75 △ Women <65 and men <75 who have additional risk factors* <p><i>If indicated by fracture risk, proceed to DXA scans</i></p>	<p><i>Consider performing FRAX or QFracture assessment in all:</i></p> <ul style="list-style-type: none"> △ Women ≥65 and men ≥75 △ Women <65 and men <75 who have additional risk factors* <p><i>If indicated by fracture risk, proceed to DXA scans</i></p>
<i>Current MBS items</i>	<i>When aged over 70</i>	<i>When aged over 70</i>

*Validated osteoporotic risk factors (excluding age): low body weight, prior fracture, smoking, frequent falling, family history of fragility fracture, excess alcohol intake

**NHMRC published these guidelines in February 2010. NHMRC approval for the guidelines is granted for a period not exceeding 5 years and as such, has expired by NHMRC standards.

***The National Osteoporosis Guideline Group published on the behalf of the Bone Research Society British Geriatrics Society, British Orthopaedic Association, British Society of Rheumatology, National Osteoporosis Society and The Royal College of Physicians UK.

What interval is recommended between DXA scans for older patients?

Studies

This question refers to the recommended interval between serial DXA scans when used as a screening tool for patients >70 years.

To address this clinical question, the evidence must answer firstly whether serial scanning actually improves fracture prediction in this population and from there, what interval is required to improve fracture prediction. The first question is best addressed by studies assessing whether fracture risk is

better predicted by subsequent BMDs than baseline BMDs. 5 relevant studies were identified and their findings were contradictory.

Hillier et al.³ (2007) prospectively measured total hip BMD in 4124 older women (mean age 72) and repeated DXA scans 8 years after. Data was collected on rates of non-traumatic hip, non-spine and spine fractures. After adjusting for age and weight change, they found that initial and repeat BMD measures were similarly associated with fracture risk for non-spine (HR=1.6), spine (OR=1.8-1.9) and hip (HR 2.0-2.2) ($p < 0.001$ for all). Stratification by initial BMD T scores (mean = -1.37) did not alter results. Hillier et al. concluded that repeating DXA scans up to 8 years later did not provide additional value to the initial BMD measurement for predicting fracture risk.

In 2012, Leslie et al.⁴ published supporting results. They measured 4498 women (mean age 65) for initial BMD, subsequent BMD and rates of major osteoporotic fracture. While the fracture group had lower final BMD, they also had lower baseline BMD and so annualised percentage change in total hip BMD was no greater in the fracture group (-0.4 ± 1.7 vs. -0.5 ± 1.4 ; $P = 0.166$). They concluded that BMD loss wasn't a significant independent risk factor for fracture.

Berry et al.⁵ (2013) performed a population-based cohort study of 310 men and 492 women (mean age 74.8) who had two femoral neck BMDs taken. They assessed rates of hip and major osteoporotic fracture in the 12 years after the second BMD. While they did find a statistically significant annualised change in BMD for both the hip fracture group (HR=1.43; 95%CI =1.16-1.78) and the major osteoporotic fracture group (HR=1.21; 95%CI=1.01-1.45), they applied ROC curve analyses and found that the addition of BMD change to a model with baseline BMD did not significantly improve performance of fracture prediction (AUC 0.71 for baseline BMD [95%CI=0.62-0.75] vs. AUC 0.72 for baseline BMD + BMD change [95%CI=0.66-0.79]). They too were able to conclude that a second BMD measure after four years did not significantly improve fracture prediction.

However, studies by Berger⁶ and Nguyen⁷ found that bone loss was an independent risk factor for fracture. Berger et al.⁶ performed a prospective cohort study on 3635 women and 1417 men aged 50-85 (mean age 64) who had fragility fractures and at least two BMDs performed within 5 years of the study commencing. They found that a decrease of 0.01 in total hip BMD per year was associated with increased risk of fragility fractures (OR=1.15; 95%CI=1.02-1.78) independent of baseline BMD. In their discussion, they identified that the older age group studied by Hillier³ (>65 years) may have excluded the patients in whom the most rapid BMD loss occurs, possibly explaining their different findings. Nguyen, Centre and Eisman⁷ assessed 966 women (mean age 70) who had at least two BMD measurements within the Dubbo Osteoporosis Epidemiology Study and followed them for an average of 10.7 years to assess their fracture rate. Similarly to Berger et al. they found that the annualised percentage change in femoral neck BMD was significantly higher in the fracture group than non-fracture group ($-1.4 \pm 4.1\%$ vs $-0.8 \pm 2.9\%$; $p=0.005$) independent of baseline BMD. However there was no significant difference in the rate of change in lumbar spine BMD between the fracture and non-fracture group ($-0.3 \pm 2.8\%$ vs. -0.1 ± 2.0). They concluded that "in this study, 45 of every 100 fractures were attributable to only three risk factors, namely, osteoporosis, high rate of

femoral neck bone loss, and advancing age. However, the attributable fraction for high rate of bone loss was modest, because the combination of osteoporosis and advancing age accounted for most of the attributable fraction. This is because the prevalence of osteoporosis (26%) was higher than the prevalence of high bone loss (10%)”.

In regards to the second question, only one study was identified as addressing the suitable interval for serial scans in an asymptomatic population over 70. Gourlay et al.⁸ studied the same 4957 women that were included in the Study of Osteoporotic Fractures by Hillier et al. 1255 women were assessed for transition from normal BMD to osteoporosis and 4215 women were assessed for transition from osteopenia to osteoporosis (513 were assessed for both transitions). In their sensitivity analysis based on BMD at the femoral neck, the covariate-adjusted times for 10% of the women to make the transition to osteoporosis was dependent on patient age group. In the >85 year age group, it took 11.8 years for the mildly osteopenic group (95%CI=9.0-15.5), 3.2 years (95%CI=2.6-3.9) for the moderately osteopenic group and 0.8 years (95%CI=0.6-0.9) for the severely osteopenic to become osteoporotic. In the 70-75 year age group, these results were 5.1 years (95%CI=4.6-5.7) for the moderately osteopenic and 1.2 years (95%CI=1.0-1.4) for the severely osteopenic. They were unable to report specifically for the mildly osteopenic group because their estimate was >15 years with a 95%CI excluding 15 years (due to the excessive extrapolation required for the figure). They did not report the transition time for normal BMD to osteoporosis by age, but the average time of transition, adjusted by continuous BMD and age was 16.8 years (95%CI=11.5-24.6). These results suggest that baseline BMD results are the best indicator for interval of repeat BMD testing.

Table C2: Clinical Practice Guidelines – intervals for patients >70 years

Group, publishing date	Recommendations
Royal Australian College of General Practitioners (RACGP) 2012	<ul style="list-style-type: none"> △ Repeat DXA scan when it is likely to change management (i.e. only when the patient is at risk of reaching treatment thresholds [average decrease in T-score is around 0.1/year if no specific bone-losing medical conditions]) △ Repeat no more than every 2 years <p>Without a bone-losing medical condition (e.g. steroid use) it is unlikely to change significantly in <2 years.</p>
National Health and Medical Research Council (NHMRC) 2010*	It is appropriate to recommend a repeat BMD by DXA after 2 years for patients at risk of developing OP, to assist in re-evaluation of fracture risk.
United States Preventive Services Task Force (USPSTF) 2011	“The potential value of rescreening women whose initial screening test did not detect osteoporosis is to improve fracture risk prediction. Evidence is leading about optimal intervals for repeated screening and whether repeated screening is necessary in a woman with normal BMD. Because of limitations in the precision of testing, a minimum of

Group, publishing date	Recommendations
	2 years may be needed to reliably measure a change in BMD; however, longer intervals may be necessary to improve fracture risk prediction.”
International Society for Clinical Densitometry 2015	Serial BMD testing can be used to determine whether treatment should be started on untreated patients, because significant loss may be an indication for treatment. Follow-up BMD testing should be done when the expected change in BMD equals or exceeds the least significant change (LSC).
American College of Physicians 2014	Repeat negative screens in two years if the result will change management.
National Osteoporosis Guideline Group** 2014	If a patient has a low risk DXA scan, they can be reassured and reassessed in five years time (or less depending on clinical context) with the FRAX algorithm, which will indicate if they have a need for repeat DXA.
National Clinical Guideline Centre UK 2012	Consider recalculating fracture risk (with FRAX or the Qfracture algorithm) in the future if the original calculated risk was in the region of the intervention threshold for a proposed treatment and after a minimum of two years, or when there has been a change in the person’s risk factors.
<i>Current MBS items</i>	<i>Currently no limit on repeat DXA scans for patients >70.</i>

*NHMRC published these guidelines in February 2010. NHMRC approval for the guidelines is granted for a period not exceeding 5 years and as such, has expired by NHMRC standards.

**The National Osteoporosis Guideline Group published on the behalf of the Bone Research Society British Geriatrics Society, British Orthopaedic Association, British Society of Rheumatology, National Osteoporosis Society and The Royal College of Physicians UK.

What interval is recommended between DXA scans for patients when receiving therapy?

Studies

This question refers to the recommended interval between serial DXA scans when used to monitor patients receiving therapy.

To address this clinical question, the evidence must firstly answer whether changes in BMD correlate with fracture reduction in this population and from there, when serial scans are recommended to improve upon management of this population.

Two meta-analyses and 1 additional clinical trial was identified that addressed whether BMD changes correlated with vertebral fracture reduction in patients receiving therapy. In 2002, Cummings et al.⁹ published a meta-analysis of 12 trials published between 1966 and 2000 that correlated improvement in spine BMD with risk reduction of vertebral fracture. They analysed all blinded RCTs assessing anti-resorptive drugs, spine BMD and vertebral fracture in postmenopausal women (n= 21,404). They found that a 1% improvement in spine BMD was associated with a 0.03 decrease in the relative risk of spine fractures (95%CI= 0.02-0.05; p=0.002) but they also noted that treatment with these agents reduces risk of vertebral fracture by more than would be predicted by BMD improvement. This correlation is supported by the meta-analysis published by Wasnich and Miller¹⁰ in 2000. They also examined 12 RCTs (7 overlapped with Cummings et al.⁹) and found that an 8% increase in spine BMD would correspond to a 0.46 decrease in the relative risk of vertebral fractures or a 54% risk reduction (95%CI= 30%-71%). They also reported that a 5% improvement in hip BMD would correlate to a 0.50 decrease in relative risk of fracture (95%CI=0.80-0.62). Like Cummings et al.⁹ they observed a protective effect from anti-resorptives than could not be explained by BMD gain but concluded that “it is not necessary that changes in BMD during treatment explain all of the antifracture effect; as long as antifracture efficacy is roughly proportional to changes in BMD, such changes will be of clinical value.”¹⁰ Hochberg et al.¹¹ (1999) performed an RCT not included in these meta-reviews that focused on the correlation between total hip BMD improvement, spine BMD improvement and vertebral fractures. They studied 2,984 women aged 55-81 on alendronate and assessed their BMD at baseline, 12 and 24 months. At 12 months, they found that 3.2% of women who had a $\geq 3\%$ increase in total hip BMD experienced a vertebral fracture, compared to 6.3% of those with $< 3\%$ increase (OR= 0.45, 95%CI=0.27-0.72). The same pattern was reported for spine BMD at 12 months and for both sites using change in BMD at 24 months. Interestingly, they found that women with the largest hip BMD improvement in the first 12 months had the lower incidence of vertebral fractures in the whole follow-up period.

One meta-analysis and one cluster-randomised study were identified that correlated improvements in spine or hip BMD with improved rate of nonvertebral fractures. Hochberg et al. (2002)¹² performed a meta-analysis on 18 trials, including a total of 26,494 women during which 2,415 nonvertebral fractures were experienced. They found that at one year, a 6% reduction in spine BMD corresponded to a 39% relative risk reduction (p=0.02) of nonvertebral fracture and that a 3% reduction of hip BMD corresponded to a 46% risk reduction (p=0.006) of nonvertebral fracture. These results were supported by a more recent study published by Eastell et al. in 2011¹³.

One RCT was found that contradicted the general consensus formed by the above meta-analyses. Sarkar et al.¹⁴ assessed 7705 postmenopausal women on raloxifene and measured both hip and spine BMD over 3 years. While they agreed that for any given percentage change in spine or hip BMD there was a statistically significantly lower vertebral fracture rate, they performed logistical regression on their data and found that percentage change in hip BMD only accounted for 4 per cent of the observed reduction in vertebral risk. While they acknowledged that accuracy errors in BMD measurements may have contributed to this finding, they concluded that changes in BMD are

correlated to reduced fracture risk but “poor surrogates”¹⁴ for predicting the actual reduction in fracture risk.

No studies were found addressing the optimum interval between serial scans in an osteoporotic patient receiving treatment.

Table C3: Clinical Practice Guidelines -monitoring

Group, publishing date	Recommendations
National Health and Medical Research Council (NHMRC) 2010*	In patients with confirmed OP, repeat BMD is generally not required, however it may be conducted before initiating a change in, or cessation of, anti-osteoporotic therapy
National Osteoporosis Foundation (NOF) 2014	Repeat BMD assessments 1-2 years after initiating therapy and then every two years thereafter, with more frequent testing in certain clinical situations. The interval between repeat BMD screenings may be longer for patients without major risk factors and who have an initial T-score in the normal or upper low bone mass range.
International Society for Clinical Densitometry 2015	Follow-up DXA should be done when the expected change in BMD equals or exceeds the least significant change (the least amount of BMD change that can be considered statistically significant), which is typically one to two years after initiation or change of therapy, with longer intervals once therapeutic effect is established. In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate
Canadian Medical Association 2010	For patients who are undergoing treatment, repeat DXA should initially be performed after one to three years. The testing interval can be increased once therapy is shown to be effective.
National Osteoporosis Guideline Group 2014**	In patients under 75 that are on bisphosphonates who have not sustained a fracture, perform a repeat FRAX score and BMD after 3-5** years of treatment and reevaluate their need for therapy. **3 for zoledronic acid, 5 for other bisphosphonates
<i>Current MBS items</i>	<i>Current interval limit for monitoring established osteoporosis (T score \leq-2.5) is 12 months</i>

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Effectiveness of FRAX scoring

Studies

Studies were considered relevant to the research question if they addressed the ability of FRAX to calculate fracture risk or if they compared FRAX to BMD in their ability to calculate fracture risk. For the purpose of this review, only studies relevant to FRAX's application on untreated patients were considered.

In 2008, Kanis et al.¹⁵ developed FRAX based on the use of clinical risk factors with or without BMD tests. They ran baseline and follow-up data from nine prospective population-based cohort studies through four models; two assessed the probability of hip fracture (with and without BMD) and two assessed the probability of other major osteoporotic fractures (with and without BMD). Fracture and death continuous hazard functions were calculated using a Poisson regression. They found that the presence of more than one risk factor increased fracture probability in an incremental manner and thus could be used to produce a fracture risk. They also found that the addition of BMD to the FRAX calculation did significantly affect the fracture risk calculated e.g. in a women aged 65 with BMI of 20, the 10-year hip fracture probability without BMD ranged from 2.3-27.9% (no risk factors to four risk factors) to 2.8-19.7% (no risk factors to four risk factors) with BMD. This suggested that while FRAX produces a reasonable fracture risk result, FRAX with BMD may produce a more specific fracture risk result.

Johansson et al.¹⁶ (2009) performed a study to validate the use of FRAX (clinical risk factors or CRFs) in 10 different prospective population based cohorts, with and without information on hip BMD. They defined sensitivity as “the proportion of individuals who would sustain a hip fracture within 10 years that were selected for treatment” and PPV as the “probability that a woman selected for treatment would fracture a hip within 10 years”. Highest sensitivity was found with BMD alone (55.9%), as compared to CRFs alone (28.7%) or CRFs and BMD combined (55.8%). The highest PPV was found with combined CRFs and BMD (8.3%) as compared to CRFs alone (5.3%) or BMD alone (5.8%). In terms of the NNT to prevent 1 hip fracture, combined CRFs and BMD was only 33, with 54 and 47 needed for CRFs alone and BMD alone respectively. They concluded that the use of CRFs and BMD together results in optimal case finding and that the use of FRAX without BMD is of some value, particularly in locations where facilities for BMD testing are limited.

In 2011, Tamaki et al.¹⁷ assessed the Japanese version of FRAX in 815 Japanese women aged 40-74. They calculated FRAX scores with and without BMD and then followed the patients for 10 years for major osteoporotic or hip fracture. They found that the AUC of FRAX without BMD for predicting major osteoporotic and hip fractures was similar to those with BMD (0.69 vs. 0.67; $p=0.121$; 0.88 vs. 0.86; $p=0.445$) and concluded the tool was efficacious in their population of interest both with and without BMD. Similar findings were reported by Cheung et al.¹⁸ in 2012. They studied 2,299 postmenopausal Chinese women who had clinical risk factor assessment and BMD at baseline and then followed them up for an average of 4.5 years for outcomes of major osteoporotic fractures.

Different models of predicting risk were compared. They found the AUC for FRAX with T score (0.729; 95%CI=0.68-0.78) was similar to the AUC for FRAX without T score (0.706; 95%CI=0.66-0.76).

Leslie et al.¹⁹ produced a retrospective cohort study of 36,730 women and 2,873 men aged over 50 years from Manitoba (Canada), to compare the fracture risk calculations produced for these patients by FRAX alone and by BMD T-score alone. They found that 85% (Canadian FRAX tool) and 83% (US FRAX tool) of the high risk patients predicted by FRAX had an osteoporotic BMD at one or more sites. They also found that <1% of individuals with high risk FRAX results had normal T-scores at BMD measurement sites. These findings were very similar across strata defined by age and sex. The study demonstrated “reassuring”¹⁹ concordance between the fracture risks of patients as predicted by FRAX and BMD but did not relate these results to prediction of actual fracture outcomes.

Table C4: Clinical Practice Guidelines – FRAX scoring

Group, publishing date	Recommendations for FRAX
Royal Australian College of General Practitioners 2015	Recommends “assessment of risk factors” and preventative advice for postmenopausal women aged >45 and men aged >50. They separately mention both the FRAX tool and the Garvan fracture risk calculator as ways to estimate absolute fracture risk.
United States Preventive Services Task Force 2011	Recommends using FRAX prior to DEXA in women aged 50-64 to determine whether they have a fracture risk ≥65 year olds (10-year fracture threshold of 9.3%)
National Osteoporosis Foundation (NOF) 2014	Non-specific: “estimate patient’s 10-year probability of hip and any major osteoporosis-related fracture using the U.S.-adapted FRAX and perform vertebral imaging when appropriate to complete risk assessment”. In addition, they recommend initiating treatment in patients with low bone mass (T-score between -1.0 and -2.5) and a 10-year risk of hip fracture of ≥ 3% OR when the 10-year risk of major osteoporosis-related fracture is ≥ 20% based on FRAX
International Society for Clinical Densitometry 2015	FRAX with BMD predicts fracture risk better than clinical risk factors or BMD alone. Use of FRAX without BMD is appropriate when BMD is not readily available or to identify individuals who may benefit from a BMD measurement.
American College of Physicians 2014	In women <65 years and men <75 years, perform FRAX to determine who requires further assessment by DXA
National Osteoporosis Guideline Group*** 2014	Perform FRAX in: <ul style="list-style-type: none"> △ Postmenopausal women with a risk factor** △ Men aged >50 with a risk factor**

Group, publishing date	Recommendations for FRAX
	If high risk, initiate treatment. If intermediate risk, refer for DXA. If low risk, reassure and reassess in 5 years or less if needed.
National Clinical Guideline Centre UK 2012	Consider performing FRAX or QFracture assessment in all: <ul style="list-style-type: none"> △ Women ≥65 and men ≥75 △ Women <65 and men <75 who have additional risk factors** <p>If indicated by fracture risk, proceed to DXA scans</p>
World Health Organisation (WHO) 2004	In Member States where BMD is universally recommended (e.g. at the age of 65 years or more in North America), the stratification of risk can be improved by consideration of clinical risk factors in conjunction with BMD.

*NHMRC published these guidelines in February 2010. NHMRC approval for the guidelines is granted for a period not exceeding 5 years and as such, has expired by NHMRC standards.

**Validated osteoporotic risk factors (excluding age): low body weight, prior fracture, smoking, frequent falling, family history of hip fracture, excess alcohol intake

***The National Osteoporosis Guideline Group published on the behalf of the Bone Research Society British Geriatrics Society, British Orthopaedic Association, British Society of Rheumatology, National Osteoporosis Society and The Royal College of Physicians UK.

Discussion

This rapid review was put together to summarise the available evidence for four key research questions related to bone densitometry. It was the intention of the Unit that the rapid review would be an accompaniment to the vast body of clinical knowledge held by the clinical committee and enable them to plan the direction of their review. Where the committee identifies an area related to bone densitometry that may be amenable to change, they should inform the Unit who will commission a complete literature review on the topic by a consultancy company. This rapid review is not intended to be a replacement for a formal literature review.

Due to time limitations on the production of this rapid review, it was not feasible for the reviewer to comprehensively assess the internal and external validity of each study. It was also decided that rather than ranking the importance of each study, the reviewer would include each study identified as relevant to the research question and present them clearly enough to allow the clinicians to assess their significance.

The review highlights a key issue for the evidence behind screening with bone densitometry; the large heterogeneity in the populations and outcomes assessed in each individual study. In studies on non-osteoporotic patients with no previous fracture, there was often limited age related data, which

is highly relevant to our research question in this population. In studies on osteoporotic patients, patients may have been selected based on their T-score, bisphosphonate use or previous fracture and measured for any number of outcomes, such as spine BMD improvement, hip BMD improvement, vertebral fracture rate or major osteoporotic fracture rate. It is thus difficult to interpret the study results cohesively, with such large heterogeneity.

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Serial scans in patients >70

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